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Status of sustainability at medical device manufacturers based in Finland

Metropolia University of Applied Sciences

Master of Engineering

Information Technology

Master's Thesis

4 November 2022

PREFACE

The report is dedicated to medical device industry colleagues. I have huge appreciation for all of you; for your contribution to today's healthcare and the stamina to continue to execute in demanding and ever-changing circumstances.

The research has been conducted in cooperation with Healthtech Finland, members of which represent medical device industry located in Finland. It is a unique, highly professional community, whose collaboration and contribution made the research possible. This is a demanding industry, and the value of this community is immense. Practical implementation of the research was supported by Howspace Oy, who provided their AI assisted cooperation platform for the research usage and thereby contributed to the mission of making healthcare more sustainable. As the society moves towards a system level change, demand for tools that involve stakeholders to facilitate engagement and change, increases. My sincere thanks go to my thesis supervisors, the whole Metropolia University of Applied Sciences, Master of Engineering, ICT, Medical Technology programme, and my study colleagues for the many fruitful discussions. I wish you all, all the best. In addition to the research and medical technology learnings, I value the learnings I gained from sustainability related studies. Education will be a key driver for wider realization of sustainable actions. I also want to express my gratitude to Metropolia Säätiö for the support provided for the research.

Finally, I want to thank colleagues and cooperation partners through the years, my dear family and friends. You broaden my perspectives, bring joy to my life, and encourage me to take steps towards the unknown future. I am grateful for the trust and support that I have experienced during my life.

In Espoo, 4th November 2022

Minna Makki

Abstract

Author:	Minna Makki
Title:	Status of sustainability at medical device manufacturers based in Finland
Number of Pages:	147 pages + 2 appendices
Date:	4 November 2022
Degree:	Master of Engineering
Degree Programme:	Information Technology
Professional Major:	Medical Technology
Supervisors:	Päivi Haho, D.Sc. (Tech.), Principal Lecturer Sandra Liede, Lawyer, Regulatory Affairs

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Modern healthcare is highly dependent on medical devices. As strategic suppliers, the sustainability of medical device manufacturers directly impacts the sustainability of healthcare. Prior medical device sustainability research offers valuable specialized expertise but lacks industry overview. By providing industry sample-based findings, the research increases comprehension of the practical status of sustainability at medical device manufacturers based in Finland. Action research approach is used to activate industry representatives to evaluate sustainability of their organization and learn how that relates to industry peers. The output is analysed against relevant academic research and other public references.

Sustainability challenges of the medical device industry include re-inventing practises to reduce environmental footprint while sustaining patient safety, and innovating means to increase equality and global access to medical devices. Medical device manufacturers have significant differences in operative implementation of sustainability. Medical device manufacturers whose mission and strategy includes sustainability are ahead of the industry peers in implementing sustainability into their operations. A sustainability deployment gap can be identified between the current industry situation and a status where sustainable medical devices are key enablers of sustainable healthcare. Based on the results, drivers towards that direction include growing customer demand, regulatory developments, management awareness and high motivation of medical device industry professionals to reshape the operations of the medical device manufacturers to become more sustainable. The research, furthermore, includes ethical considerations and notes the sustainability impact potential of large organizations in this polarized industry.

Keywords: Sustainable medical devices, sustainable medical device manufacturer, European medical device industry, sustainable healthcare, sustainability, sustainable development, SDG3 Good Health and Wellbeing, Universal Health Coverage (UHC)

Tiivistelmä

Tekijä:	Minna Makki
Otsikko:	Suomessa toimivien lääkintälaitevalmistajien vastuullisuuden tila
Sivumäärä:	147 sivua + 2 liitettä
Aika:	04.11.2022
Tutkinto:	Insinööri (YAMK)
Tutkinto-ohjelma:	Tietojenkäsittely ja tietoliikenne
Ammatillinen pääaine:	Terveysteknologia
Ohjaajat:	Päivi Haho, TkT, yliopettaja Sandra Liede, johtava lakiasiantuntija

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Nykyaikainen terveydenhuolto on erittäin lääkintälaitteista riippuvaista. Strategisina toimittajina, lääkintälaitevalmistajien vastuullisuus vaikuttaa suoraan terveydenhuollon vastuullisuuteen. Aiempi lääkintälaiteita koskeva vastuullisuustutkimus tarjoaa arvokasta erikoisosaamista, mutta siitä puuttuu yleiskuva toimialasta. Esiintuomalla toimialaotokseen perustuvia löydöksiä, tämä tutkimus lisää ymmärrystä Suomessa toimivien lääkintälaitevalmistajien vastuullisuuden tilasta. Toimialan edustajia aktivoitiin toiminnallisella tutkimuksella arvioimaan oman organisaation vastuullisuutta ja oppimaan kuinka se on suhteessa muihin toimialan toimijoihin. Tuloksien analysoinnissa hyödynnettiin aiheeseen liittyvää akateemisista tutkimusta ja muita avoimia lähteitä. Lääkintälaitetoimialan vastuullisuushaasteet sisältävät haasteen keksiä tapoja ympäristöjalanjäljen pienentämiseksi samalla kuin varmistetaan potilasturvallisuus, sekä haasteen innovoida tapoja, joilla lisätään tasa-arvoa ja lääkintälaitteiden maailmanlaajuista saatavuutta. Lääkintälaitevalmistajat eroavat merkittävästi toisistaan siinä, miten vastuullisuus toteutuu operatiivisella tasolla. Laitevalmistajat, joiden missioon ja strategiaan kuuluu vastuullisuus ovat pidemmällä kestävien käytäntöjen toteuttamisessa kuin muut. Yleisellä tasolla, on tunnistettavissa kuilu toimialan nykytilanteen ja sellaisen tilanteen välissä, jossa kestävät lääkintälaitteet ovat tärkeitä vastuullisen terveydenhuollon mahdollistajia. Tuloksien mukaan, tähän suuntaan ajavat kasvavat asiakastarpeet, lainsäädännön kehityksen suunta, johdon tietoisuus ja lääkintälaitealan ammattilaisten korkea motivaatio uudistaa laitevalmistajien toimintaa entistä vastuullisemmaksi ja kestävämmäksi. Tutkimus sisältää vastuullisuuteen liittyvää eettistä pohdintaa ja nostaa esille suurien organisaatioiden vastuullisuuden toteutumiseen liittyvät vaikutusmahdollisuudet tässä polarisoituneessa markkinassa.

Avainsanat: Kestävät lääkintälaitteet, vastuullinen lääkintälaitevalmistaja, eurooppalainen lääkintälaitetoimiala, vastuullinen terveydenhuolto, vastuullisuus, kestävyys, kestävä kehitys, SDG3 hyvä terveys ja hyvinvointi, terveyspalveluiden yhdenvertainen saatavuus (UHC)

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List of Abbreviations

CE	*"conformité européenne"* ("European conformity")
CO2	Carbon dioxide, CO 2
COP26	26th Conference of the Parties, UNFCCC
CSRD	Proposal for Corporate Sustainability Reporting Directive
DESI	Digital Economy and Society Index
EFRAG	European Financial Reporting Advisory Group
ESG	Environmental, Social and Governance
EUDAMED	European Database on Medical Devices
GRI	Global Reporting Initiative
HUS	Helsinki University Hospital
IFU	Instructions for Use
IIED	International Institute for Environment and Development
IPCC	Intergovernmental Panel on Climate Change
LCA	Life-Cycle Assessment
MD	Medical device
MDR	Medical Device Regulation, (EU) 2017/745
MHRA	Medicines and Healthcare products Regulatory Agency (in the UK)
NFRD	Non-Financial Reporting Directive, 2014/95/EU
NHS	National Health Service (in the United Kingdom)
QMS	Quality Management System
SaMD	Software as a Medical Device
SBT	Science Based Targets
SDG	(United Nations) Sustainable Development Goal(s)
SFDR	Sustainable Finance Disclosure Regulation, (EU) 2019/2088
SME	Small and Medium-sized Enterprise
TCFD	Task Force on Climate-related Financial Disclosures
UHC	Universal Health Coverage
UN	United Nations
UNFCCC	United Nations Framework Convention on Climate Change
WBCSD	World Business Council for Sustainable Development
WHO	World Health Organization

1 Introduction

In 2022, sustainability is considered as an "*Important topic. It's a bit of a buzz word nowadays but should be a real priority for companies, not just a way to try to improve company image*". This is how a professional working at a medical device manufacturer located in Finland summarized the status of sustainability in April 2022.

Recently, the general awareness has increased with regards to materialization of climate change, reduction of biodiversity and increased inequality. Also, the role high-income nations have had causing the current crisis [1, p. e346] and their role in solving it, is slowly getting acknowledged. Nations around the world and the European Union have made future related legal commitments such as the Paris Agreement in 2015 [2] and the European Green Deal in 2019 [3]. Expert updates including e.g., Intergovernmental Panel on Climate Change (IPCC) assessment reports in summer 2021 [4] and early 2022 [5] as well as the United Nations climate change conference, COP26 meeting in Glasgow [6], however, repeatedly provide evidence that the current level of activities is not sufficient, and that addressing the global sustainability challenges cannot be postponed without consequences.

Evidence exists that public and private sector actors across industries, including healthcare, have started to take action. To balance the various threat scenarios [7], also multiple positive scenarios of sustainable healthcare have been drafted e.g., by World Business Council of Sustainable Development (WBCSD) [8, pp. 64-67]. Modern healthcare is highly dependent on the usage of medical technology and thereby medical devices directly impact the sustainability of healthcare. Medical devices industry is global by nature, and thus EU originated medical devices are also used outside of the EU. According to European Database on Medical Devices (EUDAMED), there are 261 manufacturers operating in Finland [9].

The research aims to increase the understanding of the status of sustainability of medical device manufacturers based in Finland. This includes companies that have headquarters in Finland as well as foreign companies with operations in Finland. The secondary target of the research is to support, activate, and encourage all medical device professionals regardless of their role or location, to learn more, and take further sustainability actions. The research data collection was conducted as an interactive online survey during which medical device industry representatives were able to provide their views on their organization's sustainability and immediately thereafter see how it relates to the views of industry peers. The research gathers views of about 30 quality and regulatory assurance professionals of Healthtech Finland member organizations belonging to Medical Device workgroup. The sample includes various size of companies from large to microenterprises, companies that also differ from each other regarding how long they have been regulatory compliant medical device manufacturers, and where their customers and headquarters are located.

In the report, first the research question, methods and data are introduced. Thereafter, brief background information is provided relating to the contextual framework to which the research contributes to. Results and Findings forms the largest part of the report. That section includes views of the representatives of medical device manufacturers based in Finland, followed by immediate brief analysis. The Results and Findings section covers the following themes: United Nations Sustainable Development Goals (UN SDGs), Strategic Importance and Management Commitment, Sustainability of Operations, Sustainability related Risk Management and Sustainability related Resources. Thereafter the main conclusions and implications to the context are discussed. That section considers limitations of the research, and projects the possible impact of the research on medical device industry and later research. Appendices and references to literature sources are presented at the end of the report.

2 Research Question, Method, and Data

This chapter will introduce the research question, the methods, and data. The information on data collection and analysis will provide a perspective to the Results and Findings introduced later.

2.1 RESEARCH QUESTION

The scope of the research is to gain understanding of the status of sustainability in medical device industry by researching medical device manufacturers based in Finland. The precise research question is:

What is the sustainability status of medical device manufacturers based in Finland?

Medical device industry key drivers include industry specific regulation and customer needs. Regulatory requirements for this specific industry do not conflict with but do not address wider sustainability issues explicitly either. Global customers, representing the social and healthcare industry have their ongoing challenges, and have furthermore been pushed during the past years due to the covid-19 pandemic. In the past couple of years, medical device manufacturers in the EU have adjusted to new industry regulation [10] and have also operated under special pandemic conditions which has impacted e.g., their production, their logistics and raw material availability, as well as business, as customers have addressed the most burning issues and postponed future oriented non-urgent investments.

Considering this, what is the sustainability status of medical device manufacturers? How do the medical device manufacturers address the UN Sustainable Development Goals? How proactive the medical device manufacturers have been? How do their actions contribute to the sustainability of healthcare industry? More specific questions include:

- What is the top management's level of competence and commitment to sustainability? Is sustainability integrated into the medical device manufacturers' mission and strategy?
- To what extend are the current operations sustainable?
- How is the sustainability risk management situation at medical device manufacturers?
- Do the medical device manufacturers have competencies and financial resources to address sustainability issues?
- Are there any hints, when and how increased attention to sustainability could materialize? Who or what could drive it? Who could be the leaders in this space?

Answers to these questions are currently not available, nor systematically collected by any instance.

Yet, medical device manufacturers are in the key position to impact the sustainability of the whole healthcare industry, in the EU and beyond. For example, due to the changed geopolitical situation in Europe, energy consumption has become a common discussion topic in 2022. Medical device manufacturers can impact, in the design phase, energy consumption of their devices, which has a cumulative impact on the energy consumption of the healthcare industry. Similarly, medical devices contribute to the pollution emissions of the healthcare industry, which ironically have adverse effects on public health [11].

The outcome of the research aims to trigger wider discussion on medical device manufacturers' role in addressing the sustainability of healthcare. For that purpose, it aims to get an overview of the sustainability status of current operations, how sustainability related risks are currently managed, as well as overview of the human and capital resource situation. Without this information, the industry professionals, and policy makers, lack the industry status overview.

The regulatory bodies in the European Union are committed to drive global sustainability transition [2] [3] [12] [13]. How are the medical device manufactures based in Finland contributing to that? Despite the country specific differences, due to common legislation base that has strong impact on the industry, the results will also provide an indication of the status of sustainability at medical device manufacturers operating in the European Union.

2.2 METHOD AND DATA

Due to recognized global need to raise higher awareness for sustainability issues and more specifically the need to encourage the medical device community to act proactively, the chosen methodology for the research is action research.

The choice of methodology is aligned with the philosophy universities of applied sciences to contribute and closely cooperate with society to address topical challenges. Action research is considered to contribute to sustainability related learning and cultural transformation [14] by affecting actions taken by individuals. Wittmayer et al. argue that action research provides a promising approach to face the necessary sustainability transition [15].

To answer the research question, and to involve and activate the medical device industry, the research was conducted in cooperation with Healthtech Finland, a non-profit industry association, members of which provide a valid representation of the medical device industry based in Finland [16]. The research involves the target audience, professionals working in medical device industry, already in the data collection phase, not as passive respondents but as active discussion participants, and contributors to the analysis of some of the results. To collect the data efficiently and to reach the essential target to activate and engage the target audience, an interactive survey was conducted as a workshop in cooperation with Healthtech Finland on 26th April 2022.

All participants in the workshop were members of Healthtech Finland community. The respondents represented a mix of large companies, small and medium size

companies (SME) and microenterprises. Similarly, the sample of companies included companies that are well established, regulatory compliant medical device manufacturers as well as companies that have more recently become compliant with the EU regulatory requirements for medical device manufacturers, as well as a couple of companies that were still in the process of becoming regulatory compliant.

Some medical device manufacturers participating in the workshop also had a role of medical device distributor and / or healthcare service provider. A marginal minority of the respondents consisted of medical device industry specialized consultants and parties with some other medical device industry role. Some organizations had headquarters in Finland whereas others were subsidiaries of foreign medical device manufacturers. About a third of the participating companies had customers in the EU, another third had customers in the EU, North America and elsewhere, and the last third had customers in the EU and outside of the EU, but not in North America. Respondents provided the above kind respondent profile information themselves by selecting from given alternatives. In the report, respondents are collectively referred to as (workshop) participants and / or respondents or (representatives of) medical device manufacturers based in Finland. For sake of simplicity, all organizations are referred to as medical device manufacturers or companies.

The interactive survey was conducted during a workshop, and it consisted of three parts, each of which were briefly introduced by the researcher:

- Sustainable Development Goals
- Sustainability related Risks
- Status of Sustainability

Attention was paid to conduct the section introductions as briefly and neutrally as possible, referring to generally acknowledged publicly available data including UN Sustainability Goals [17], MedTech Europe statistics [18], brief introductions to sustainability terminology and European Green Deal [3]. The reason to include

these brief introductions were two-fold 1) to put all respondents “on the same page” and 2) to facilitate a rewarding workshop experience.

Each section included questions, which were answered at the same time by all participants. Due to the workshop setup, there was a time limitation to answer each question section, however, it was also made technically feasible to complete answers afterwards. Also, respondents were technically enabled to change their initially given answers at any time if they so desired.

An AI assisted interactive online communications platform was used as a survey tool which enabled the participants to get immediate feedback on how their responses were in relation to the responses of industry peers. The survey structure included both open ended questions and multiple-choice sections which aimed to complement each other.

In the multiple-choice sections, the participants of the workshop were provided with statements, and they were given multiple-choice options either to “fully agree”, “partially agree”, “fully disagree” or “partially disagree” with the given statements, or to select “do not know or not relevant” option if they considered that to be the most appropriate alternative. The statements were provided to the workshop participants in random order and have been categorised and organised in the data analysis phase. Some of the statements were deliberately chosen to be similar or interlinked to test the consistency of the answers provided by the respondents and to provide further insights to the result analysis.

Before the start of the workshop, the respondents gave permission for the usage of the data for research purposes, with the condition that individual's name or organization’s name will not be referred to in the research report. Due to the possibly sensitive nature of the topic, the workshop was implemented in way that respondents could provide their answers so that their names or organizations, or other information about the respondent was not visible to the other respondents. The approach was chosen, to encourage honest answers, so that the output

would benefit and take forward individual companies and the whole healthcare industry.

The interactive survey structure was implemented in way that respondents were not forced to provide answers to all questions, thereby the number of respondents per question varies a little bit. On average there were about 30 respondents. According to European Database on Medical Devices (EUDAMED), there were 261 medical device manufacturers based in Finland [9]. The response rate is aligned with the 16% response rate of FIBS Sustainability in Finland 2021 survey [19, p. 10]. FIBS is the largest corporate responsibility network in the Nordic countries and their annual survey is the most comprehensive industry sustainability survey in Finland [19]. As the survey was conducted as an online workshop, there were also additional members of the industry who chose to follow the workshop but decided not to contribute actively. This implies wider general interest in the topic.

Limitations of the research include that the participation in the workshop and the interactive survey were voluntary. A larger sample size could have provided a wider view and further insights. Martínez-Mesa et al. argue that whereas insufficient or small sample size may not lead to representative representation, implementation of very large samples may in many cases turn out to be practically unfeasible and thereby both extremes are ethically unacceptable [20].

To participate in the survey, the respondents' employer had to be a member of Healthtech Finland, and the respondent had to be a listed member of the Medical Device (MD) working group. There was no participation criteria or obligation to particate, but participants self-selected to participate. If the research results have a slightly biased edge, it is due to the sample of participants potentially being more interested in the sustainability theme than members of medical device industry based in Finland on average.

As the sustainability and sustainability risk theme had not been discussed earlier within that working group, and the interactive online tool and working method may

have been new, some potential respondents may have hesitated to contribute due to these reasons. There was no feedback about this, but usually the working group meetings consist of expert presentations followed by some discussion, thus this type of workshop approach was new in this context.

Except for one respondent, all respondents had a quality and / or regulatory assurance role in their organization. This impacts the answers in two ways 1) the respondents have higher than average general understanding on the status of the operations within their companies 2) the respondents role impacts their points of view. Three participants had, in addition to the quality and regulatory assurance role, other responsibilities.

Post workshop data analytics was conducted using features of an AI assisted tool to the extent possible. The Results and Findings chapter of the report includes systematic analysis of answers provided by all participants. Additional insights were received by analysing further selected data based on the background data provided by the respondents including company type, headquarter location, size of organization, regulatory compliancy maturity of the company, customer locations and respondent's role. Size of the organization turned out to be the most insightful point of view whereas e.g., information where the customers are located did not, based on the analysis, provide further understanding to the answers provided by the respondents. Closer analysis focused on organizations at which, based on the respondents' answers, sustainability is part of the company's mission and strategy. This was conducted to gain understanding of practical implications the strategic importance of sustainability might have.

The researcher has worked as Customer Experience and Quality Lead at a small medical device manufacturer. She has hands-on experience in setting up Quality Management System (QMS) and reaching and managing medical device manufacturer compliance with EU's CE and Brazilian Health Regulatory Agency Anvisa's requirements. The role of the researcher in this action research is primarily that of reflective scientist with some change agent elements [21, pp. 487-489]. Based on the researcher's prior multi-disciplinary leadership and

business experience gained at innovative technology companies, the scope and content of the research are furthermore impacted by the new learnings from the medical technology focused engineering and sustainability studies. Her special interest during the studies has been reflecting the development of EU sustainability related legislation on the medical device industry.

The outcome of the research project, this report, is primarily targeted at medical device industry colleagues regardless of their role.

3 Background

This chapter aims to provide the readers with a high-level framework relating to the context to which the research contributes to. Starting from discussing the global need for sustainability, the chapter discusses Europe's approach to address sustainability challenges, giving a closer look at Finland. Thereafter sustainability of healthcare industry is briefly covered, before introducing previous research relating to medical device industry. Due to the immensity of the context, the theoretical framework stays on high-level, and aims to provide some relevant references and background to the motivation to understand the status of sustainability of medical device manufacturers in Finland.

3.1 GLOBAL NEED FOR SUSTAINABILITY

"We are facing a global crisis. We are totally dependent upon the natural world. It supplies us with every oxygen-laden breath we take and every mouthful of food we eat. But we are currently damaging it so profoundly that many of its natural systems are now on the verge of breakdown." This is how David Attenborough summarises the situation in the foreword of The Economics of Biodiversity: The Dasgupta Review [22, p. 5]. The Global Risks Report 2022 ranks climate action failure, extreme weather, and biodiversity loss as the top three most severe risks over a 10-year horizon [7, p. 14].

The Limits to Growth, published in 1972, raised awareness and questioned the earth's ability to accommodate the demands the economic and population growth set [23]. In 1987, the United Nations Brundtland Commission summarized: *"Humanity has the ability to make development sustainable to ensure that it meets the needs of the present without compromising the ability of future generations to meet their own needs."* [24, p. 16].

Recently the academic world has taken more prominent role in the protection of human and planetary health. Economist Sir Dasgupta reached global attention in 2021 by clearly pinpointing how human health and well-being is connected to the

health of the nature including preservation of biodiversity [22]. As an economist he calls for a balance between demand and supply: The society needs to ensure that demands on Nature cannot exceed Nature's sustainable supply, because *"thriving natural environment, underpinned by abundant biodiversity, is our ultimate safety net"* [25].

In addition to threatened biodiversity, with population of species dropping by 68% between 1970 and 2016 on global level [26, p. 16], also other so called planetary boundaries introduced in 2009 [27] are now in a critical status [28]. For example, in 2022, the planetary boundary relating to release of so-called Novel Entities was exceeded. Novel entities cover emission of toxic and long-lived substances e.g., synthetic organic pollutants, heavy metal compounds and radioactive materials which are "novel" in geological sense. The research of Persson et al. highlights particularly that plastic pollution is on a concerningly high level [29].

IPCC AR6 Summary for Policymakers describes a grave situation. *"Human society causes climate change. The rise in weather and climate extremes has led to some irreversible impacts as natural and human systems are pushed beyond their ability to adapt"* [30, pp. 6, 9]. The 2022 Global report of Lancet Countdown [31] was introduced with a statement: ***"****The health of people around the world is at the mercy of a persistent fossil fuel addiction* [32]**.** Climate change has already provenly caused adverse health effects. In addition to heat related mortality, various climate related diseases have been reported with high confidence including food-borne and water-borne diseases and emerge of zoonoses in new areas. Volatile weather conditions including increased rain and flooding have caused occurrence of diarrheal diseases including cholera and other gastrointestinal infections. Wildfires and atmospheric dust have been linked to cardiovascular and respiratory distress. Extreme climate events and related loss of livelihood and culture has also impacted mental health of many [30, p. 11] and research on the topic is evolving [33]. *"Across sectors and regions, the most vulnerable people and systems are observed to be disproportionately affected"* [30, p. 9]. Whereas Africa is one of the lowest greenhouse gas emitters, it has already suffered severely from the climate change [5, p. 1289]. Among the most

vulnerable physically and mentally are the children and young people. In a research surveying 10,000 children and young people, in 10 countries around the world, over 45% of the young respondents said that feelings caused by climate change negatively affect their daily life and functioning. Up to 75% of the young people, consider their future to be frightening and 83% view that people have failed to take care of the planet. [34]

The increased general sustainability concern has contributed to the emergence of an increasing number of various international and national initiatives of various sizes that aim to contribute to the *"shift from pledging to implementing on scale and on time*" as the targets of COPS27 well summarize the need [35]. The United Nation's 17 Sustainable Development Goals (SDGs) include aspirations for socio-economic improvement in addition to the environment related goals [17]. Randers et al. have modelled different scenarios on how reaching most of SGDs within most of Planetary Boundaries could be possible. The most influential measures are estimated to be related to reduction of carbon emissions through transition to renewable energy, more productive sustainable food chains, innovative development approaches for low-income countries, reduction of inequality, and investment in e.g., education and health. Health is therewith acknowledged to be one of the key enablers for making the other changes possible. [36, p. 7] Climate Resilient Development model of IPCC AR6 has also human health and well-being, equity and justice in its heart [30, p. 6].

3.2 SUSTAINABILITY IN EUROPE

Just prior COP25 (25th Conference of the Parties, an annual summit of the United Nations Framework Convention on Climate Change (UNFCCC)) taking place in December 2019 [37], the European Parliament declared a climate emergency in November 2019 [38]. This was followed by the European Green Deal which was announced in December 2019. The European Green Deal is Europe's written commitment and roadmap to care for nature and reaching climate neutrality as the first continent by 2050, while at the same time boosting economic growth that is decoupled from the usage of virgin resources. In the introduction of the

European Green Deal, the commission writes *"The atmosphere is warming, and the climate is changing with each passing year. One million of the eight million species on the planet are at risk of being lost. Forests and oceans are being polluted and destroyed"* and summarizes the responsibility of the current generation to be no less than*: "tackling climate and environmental-related challenges is this generation's defining task".* The European Green Deal also contains social sustainability goals: it targets at *"improving people's health and quality of life"* and makes a bold promise of *"leaving no one behind".* [3]

The EU continuously introduces new legislative initiatives to implement the Green Deal [12]. March 30th, 2022 was one significant date as the European Commission adopted a package of measures to make sustainable products the norm in the EU. Among the measures was a proposal on Ecodesign for Sustainable Products Regulation. According to European Commission's definition "*ecodesign means the integration of environmental sustainability considerations into the characteristics of a product and the processes taking place throughout the product's value chain"* [39]. Until the proposed regulation becomes effective, the current Ecodesign Directive 2009/125/EC focusing on energy-related products is effective [40]. At the time of writing, medical devices are not included in the listing of energy-efficiency products [41].

So far, large companies based in the EU have been obliged to conduct sustainability related reporting under so called Non-Financial Reporting Directive (NFRD) [42]. As it has not resulted in desired level of impact, nor comparable information, legislative initiatives within EU aim to direct the financial resources towards companies that operate in a sustainable manner [12]. One key proposed initiative is Corporate Sustainability Reporting Directive (CSRD) that is initially targeted at large and listed companies, but ultimately will also impact smaller companies either indirectly and / or directly [43].

3.3 SUSTAINABILITY IN FINLAND

Finland is one of the countries that has been rewarded as leader in sustainability. [44] Similarly, Finland has received top rankings in World Happiness Reports [45] and continues also to be an EU frontrunner based on Digital Economy and Society Index (DESI) [46]. In almost all state-owned companies, sustainability is a management and personnel reward criteria [47]. In the private sector, Finnish companies increasingly include sustainability perspectives into their communications. According to FIBS, that has systematically researched sustainability of largest Finnish companies for multiple years, the general sustainability trend is positive: sustainability work is more goal oriented, organized, measured and effective than earlier. Yet still, according to the research published at the end of 2021, sustainability is not recognized as a source of product or service development innovation. [19]

Voluntary National Review towards the SDGs conducted by the Finnish Prime Minister's Office in 2020 summarized that the country is "close to reaching" multiple social and economic SDGs. Yet, *"Finland's key challenges are related to consumption and production patterns, climate action and the state of biodiversity. Obesity is an increasing problem. Gender equality challenges, such as gender-based violence and labour market disparities, including a gender pay gap still remain. Finland's biggest challenges in the SDG implementation are related to the need for changes in consumption and production patterns, climate action, and the conservation of biodiversity."* [48]

3.4 HEALTHCARE AND SUSTAINABILITY

The focus of healthcare is on people. Patient safety is paramount, a common value shared by all involved. Importance of healthcare to society is commonly acknowledged as availability of healthcare and the quality of it directly impacts human health.

Figure 1 visualizes interconnections between healthcare, human health and wellbeing, and planetary health. Health and well-being are the engine of any human action, and therefore healthcare is a crucial support element for realization of social and environmental sustainability.

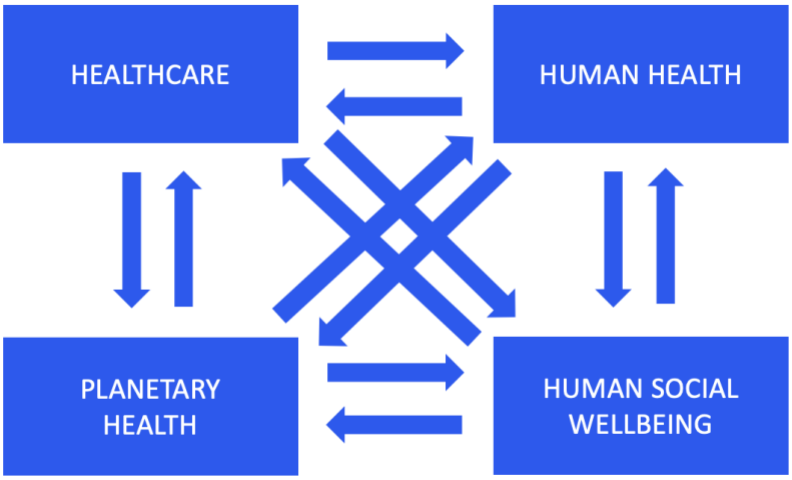

Figure 1: Interconnections between healthcare, human health and wellbeing, and planetary health

Availability of healthcare personnel, their competence, motivation, and health are underlying key elements for successful delivery of healthcare. Lack of sufficient number of competent healthcare professionals is a challenge faced by not only low-resourced countries, but also by the high-income countries with aging populations. Under-resourcing and constant time pressure impact the physical and mental health of healthcare personnel. The recovery from additional burden that the covid-19 pandemic put on the healthcare personnel is still not over, and that has impact on healthcare.

Interconnection between health and social well-being is general knowledge. Healthcare personnel is well-aware, that social suffering can cause health problems, mental and physical. In healthcare, increased understanding exists that in addition to patient care and experience, also experience and wellbeing of other stakeholders (healthcare professionals, family and other close contacts of an individual, and the wider society) are important. Yet, the focus rightfully remains on the individual in need of healthcare services.

Connection and the dependency relationship between planet earth's wellbeing and its inhabitants' health and wellbeing, has been increasingly acknowledged and researched providing *"overwhelming evidence on health impact of climate change"* [49]. The Lancet, one of the best-known general medical journals, founded already in 1823, established in the beginning of 2017 a Planetary Health section for related research publications. Planetary health was defined as "*health of the human civilisation and the state of the natural systems on which it depends"* [50]. Planet's deteriorating health adversely impacts health and wellbeing of people [30, pp. 6, 9], which sets new pressure and demands on healthcare. A less discussed connection is the role of nature as source of healthcare innovations, potential of which is still to be fully discovered. Current nature inspired medical technologies include for example parasitic wasp-inspired needles [51].

Healthcare also has a sizable environmental footprint of its own. The total global environmental footprint of healthcare is challenging to measure but estimated to be 1-5% of total global impacts, depending on the indicator, and more than 5% of some national impacts [52, p. e273]. Gathering and provisioning of organizational bottom-up information is key to making the higher-level estimations.

Healthcare's proportion of national carbon emission has been a topic of interest for the activists [53] and the researchers, with estimates ranging from 4% in England, to 7% in Australia and to 10% in the USA [54, p. 1]. In 2019 at NHS, carbon footprint of the NHS' supply chain was the largest sub-contributor with 62% of the NHS total carbon emissions versus 24% of direct delivery of care, 10% staff commute and patient and visitor travel, and 4% from commissioned private health and care services [55, pp. e87-88].

Pollution and health progress update from 2022 reveals that pollution alone causes one in six deaths worldwide totaling approximately 9 million deaths per year. The report furthermore highlights that pollution, climate change and

biodiversity loss are closely interlinked, and that pollution should not be seen as a local issue of low and middle income countries but a planetary threat calling for global action. [56, p. 1] Unintended consequences of healthcare provisioning include adverse effects on public health, as healthcare is a significant emitter of environmental pollutants [11]. World Health Organization (WHO) estimates that some 15% of all healthcare waste is infectious, toxic, or radioactive and thus hazardous and has potentially adverse health effect [57].

Whereas, COP26 caught global attention, the fact that during COP26, only 50 countries committed to developing climate smart healthcare [58] and that most European countries are missing from that list, did not get wide public attention. *"Overwhelming evidence on health impact of climate change"* [49] - a statement backed up by a wide research community, sends a strong message to the healthcare community. In 2020 still in over 60% of countries there was no national health emergency framework implementation that could be used in case of pandemics or climate-related health emergencies [49, p. 1620].

All activities have environmental footprint. The earth's temperature keeps rising, and any efforts can only reduce its speed. Healthcare needs to be prepared for different scenarios and have adaptability and resilience to reduce vulnerabilities and protect health around the world. Thinking and cooperation beyond national borders is needed as *"no pandemic nor the climate change respect national borders"* [49, p. 1621].

Even if clear evidence exists that healthcare delivery needs to become more sustainable, it remains unknown how soon e.g., integration of planetary health into clinical guidelines [59] becomes a reality.

3.5 MEDICAL DEVICES AND SUSTAINABILITY

3.5.1 Medical Device Industry in a Nutshell

Medical devices, as defined by European Medical Device Regulation (MDR), includes a large variety of instruments, apparatus, appliances, software, implants, reagents, material, and other articles [10]. The devices are used in hospitals and clinics as well as at home and care service environments. About 34,000 medical technology companies (including manufacturers of medical devices and in vitro diagnostics devices) operate in Europe, employing over 800,000 people (in comparison to e.g., 840,000 in the pharmaceutical industry). With over 500,000 products in the market, the European medical technology market was valued at €150 billion in 2021, and with 27,3% of the global market share it is the second largest market after the USA. [18]

The industry is among one of the most regulated industries within the EU. Prior to market access being granted, significant capital investments are required for development of regulatory compliant devices. Due to the nature of the industry, patient safety and data security, and therefore risk management, are at the heart of operations. The regulative requirements for medical device manufacturers are the same regardless of the manufacturer's size. In addition to the industry specific regulations on processes, and on the device itself, the medical device manufacturers also need to comply with other, sector agnostic regulations. The regulative requirements have strong impact on resource usage in the medical device industry, regardless of the size of the company. To protect the R&D and regulatory compliance investments made prior to market entry, patent applications are made. Medical technology is currently the second most patented technology industry in the EU, bypassing e.g., pharmaceutical industry [18], an industry known to be driven by patent ownership.

Up to 95% of medical technology companies in Europe, including medical device manufacturers, in vitro diagnostics, are small and medium sized enterprises (SME)s, employing fewer than 50 people [18]. These companies are often

founded on research innovation, often focused on a single therapeutic area [60]. For multiple reasons these companies do not grow beyond their size and/or are acquired by larger companies.

Despite the large number of small companies, the global medical device business is dominated by the remaining 5% of companies. Medtronic alone has a global medical technology market share of 5,8% [61]. The total turnover of top 30 medical technology companies totals around *$*300 billion [62].The figures are indicative, as information on the largest medical device manufacturers global market shares are not widely or openly shared information, and results vary per information source. The ways companies categorize their business units differs from their competitors, making direct comparison more demanding. Some statistics are provided for medical devices [63], others on medical technologies [61]. In some cases, medical device manufacturers' revenues originate also from other sources, for example in the case of Johnson&Johnson and Novartis from the pharmaceutical industry [64].

The industry analysts project the global medical device market to grow tremendously "*from $495.46 billion in 2022 to $718.92 billion by 2029 at a CAGR of 5.5% in forecast period, 2022-2029"* [65]*.* Growth is expected to come primarily from serving the needs of aging populations, treating e.g., impaired vision and joint fractions, and chronical disorders such as diabetes and cancer, and launch of easy-to-use devices that can be used in home setting reducing the costs associated with hospital care. Additionally, *"growing per capita health expenditure in developed and emerging countries"* and "*improving reimbursement policies*" are expected to contribute to the growth of the revenues. [65] Technological advancements in multiple therapeutic areas have been significant during the past decades and the role of software has grown.

Digitalization, wider usage of healthcare data in combination with advanced algorithms, transition towards more preventive and value-based healthcare are all expected to disrupt the industry further in the coming years. Among others, the giant global technology companies including Amazon, Apple, Google, and Meta

are all interested in business opportunities offered by healthcare and have, during the past decade been investing in getting access to healthcare data and development of medical technologies.

3.5.2 Medical Devices as Key Influencers of Healthcare Sustainability

In the eyes of a sustainability aware healthcare organization, *"medical devices can be considered both a solution and a problem",* as one representative of a healthcare service provider organization very well summarised in a seminar in 2022. Today's western healthcare is highly dependent on medical devices. A very simplified figure aims to visualize that no contemporary western clinic or hospital operate without medical devices, and to treat the patients' needs healthcare professionals rely, in addition to their and their colleagues' competence and care, on infrastructure (including materials, products, and services), pharmaceutics, and medical technologies. (Figure 2) Sustainability of medical devices have a direct impact to sustainability of healthcare.

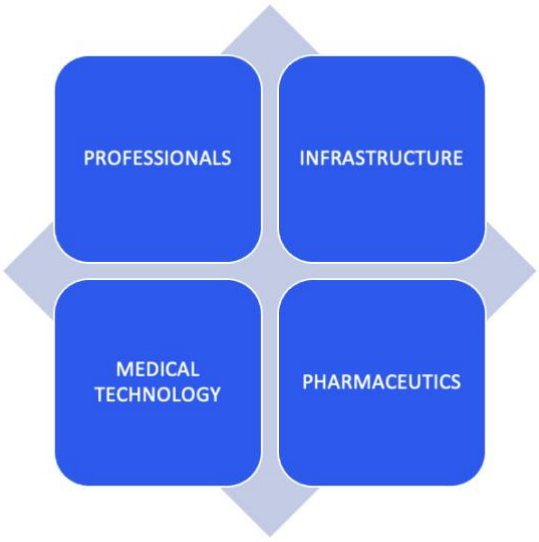

Figure 2: Simplified view of contemporary healthcare elements

During the covid-19 pandemic acts of medical device manufacturers contributed to wider social impact. In addition to regular operations, e.g., new diagnostics tests were rapidly developed, and innovative cross-sector product development

and crisis management initiatives were established to solve ventilator shortage challenges [66]. If a medical device manufacturer operates sustainably and transparently, and provides medical devices which are designed to be durable, reusable, repairable and recyclable, such a supplier can be a valued partner to a healthcare organization. Medical devices can furthermore offer means to optimize of the use of available human resources when addressing the challenges relating to global shortage of healthcare professionals [67].

Medical devices can also end up being a problem for a healthcare service provider. Lifetime of the device, set by the manufacturer, focusing on patient safety, may turn out to be too short in practise and functional devices end up “too soon” to be a waste management or recycling challenge of the healthcare service provider, as newer, improved patient safety product versions get introduced by the vendors.

Medical devices have not until recently been faced with similar customer requirements as many other industries when it comes to e.g., energy usage. Due to efficiency gains in other areas, the proportional share of medical device energy consumption in the total energy consumption is increasing. Significance of this is growing also from financial point of view as cost of energy has been increasing. Medical device manufacturers may not have, until recently been asked to provide in their proposals sustainability related details such as stand-by energy usage, ease of recyclability of the materials used in the device and packaging etc.

It is to be expected that also medical device manufacturers will at some point, be asked to comply with the codes of conduct of their customers, pass sustainable supplier assessments, and provide e.g., evidence or their progress towards reduction of CO2 emissions goals. These are not trivial requirements and e.g., NHS has recognized that especially for SMEs, and voluntary, community and social enterprises, it may take a longer time to adjust to the new requirements and it has thus granted a grace period for these suppliers [68]. Customers of medical device manufacturers can find themselves between a rock and hard place as the regulatory requirements start to push them to take wider

environmental accountability of their actions, and when it comes to selecting medical devices that support that, they are restricted to the available supply. Customers up to now may not have demanded environmental sustainability, as the primarily need remains to have devices to address the clinical needs and protect people's health, in all circumstances.

Proactive medical device manufacturers have voluntarily chosen to comply with standards such as ISO 14001 [69], frameworks such as e.g. Science Based Targets (SBTs) [70] or joined initiatives such as e.g. UN Global Compact [71] or World Business Council for Sustainable Development [8]. Particularly large organizations with existing regulatory reporting requirements have a track record of producing sustainability reporting based on frameworks of their choice, such as e.g., widely applied Global Reporting Initiative (GRI) established already in 1997 [72] and Task Force on Climate-related Financial Disclosures (TCFD) that has gained more popularity during the past couple of years [73]. Furthermore, participations in various ESG ratings are used to communicate desired excellence in this area.

Whereas, the EU has chosen to address sustainability with a sector agnostic approach, The Medicines & Healthcare products Regulatory Agency (MHRA) in the UK, with the mindset that *"Climate change is a health emergency*", has investigated the need of industry specific environmental requirements for medical devices. Due to the importance of securing that potential measures will not only drive better environmental outcomes but also compliment or enhance (and therewith not endanger) patient safety, the decision in June 2022 was made not to introduce new industry specific requirements at that point of time to avoid setting duplicative requirements. Instead MHRA stated that it considers publishing best practice guidance that is aligned with NHS Net Zero Supplier Roadmap and UK government Net Zero Ambitions. [74] Despite the Brexit, the UK remains a key European market [18, p. 28] and an influencer of the European medical device industry.

3.5.3 Medical Device Related Sustainability Research

Sustainability of medical device manufacturers can first be observed from the perspective of whether they address relevant global sustainability challenges. Another perspective is to evaluate the sustainability of the medical device manufacturers' operations.

United Nations SDG3 targets include the health and well-being related global needs [17]. Unmet Medical Needs can be found around the world [75]. World Health Organization has for a long time tried to bring attention to the public health needs of low-resource countries and tried to match those with medical devices that could improve the health outcomes or offer a solution to an unmet medical need [76] [77]. In addition to the inequality in the availability of medical devices, an imbalance between research needs and research efforts remains. Both public research as well as global industrial research and development concentrate on diseases affecting high-income countries [78].

Sustainability of medical devices has been researched from many points of view. Examples of medical device sustainability research includes e.g., studying sustainability and resilience of medical device supply chain during the covid pandemic [79], how sustainability can be incorporated to decision making of medical device development [80], the environmental impact of e.g., polymers, a commonly used material in medical devices [81] and repurposing of devices for low resource countries [82].

Similarly, medical device related sustainability research has been conducted with a particular clinical focus e.g., on single use endoscopes [83], or on impact of biofeedback on mental health [84] or on environmental sustainability of delivery of eye-care services [85]. Some research focuses on very particular aspects e.g., appropriate usage of models that represent the patient population in the medical device marketing material [86].

Auer et al, investigated research and innovation activities of the Austrian medical device sector in 2017. At the time, sustainability thinking in the form of Responsible Research and Innovation was a new concept to the interviewed medical device manufacturers. [87] A UK study in 2019 focusing on product claims made by medical device manufacturers concluded that medical device manufacturers were not at the time considering sustainability in their medical device development but rather prioritized costs and efficiency. Claimed sustainability benefits of medical devices were related to resource efficiency and cost savings. [88]

Prior research relating to medical device and sustainability addresses primarily specific use cases and therefore the overall current view of the sustainability status of medical device industry is lacking. Medicines and Healthcare products Regulatory Agency (MHRA) in the UK mapped in 2022 views and environmental sustainability actions of medical device manufacturers based in the UK and found out that the existing measures included initiatives relating to carbon emission reduction, waste management, eco-design, sustainable transport strategies, reduction of hazardous materials, sustainability and circular strategies as well sustainable procurement [74]. Except for this environmental sustainability focused survey, industry parties have not systematically collected or shared industry sustainability status information. This is expected to change. In the meanwhile, this research aims to contribute to filling that gap and to provide topical medical device industry specific insights and to contribute to the industry specific sustainability actions.

4 Results and Findings

Results and Findings chapter introduces and analyses the results of the interactive survey conducted in cooperation with Healthtech Finland during a sustainability workshop in April 2022.

4.1 SUSTAINABLE DEVELOPMENT GOALS (SDGS)

This section provides an overview of views of representatives of medical device manufacturers based in Finland on how their organizations contribute to United Nations Sustainable Development Goals.

4.1.1 Impact Assessment Towards United Nations Sustainable Development Goals

In addition to nations, many organizations have chosen, and communicate, to which United Nations Sustainable Development Goals (UN SDGs) they strategically want to contribute [17]. Also, various medical device manufacturers have made UN SDG related statements e.g., Siemens Healthineers communicates that *"Contributing to the United Nations Sustainable Development Goals (SDGs) is a priority of our business strategy"* [89]. The UN Global Compact is an initiative targeted at companies. The initiative encourages companies to act responsibly and to solve the SDG related challenges. It also challenges companies to widen their thinking and keep in mind that *"good practices or innovation in one area cannot make up doing harm in another"* [71].

To introduce the topic of sustainability to the workshop members, the United Nations 17 Sustainable Development Goals (SDGs) were briefly presented. The participants thereafter had an opportunity to mark the sustainable development goals their employer contributes to either positively or negatively and whether that impact is indirect or direct. The approach is similar to the one used with e.g., the SDG Impact Assessment Tool [90]. 21 respondents replied to this section. In addition to an introduction of the sustainability theme to the participants, this part

aimed to activate the participants to comprehend the multitude of various SDGs and how their company fits to the bigger picture.

As all the respondents were contributing members of the wider healthcare industry, it was not surprising, that the SDG to which medical device industry in Finland has the most positive impact is *SDG3: Ensure healthy lives and promote well-being for all at all ages.* It is, however, interesting to note that not all respondents had chosen that their organization would have a direct positive contribution to this SDG. This may be for the following reasons: The respondents may have felt that their organization does not contribute to all what is included in this goal "*ensuring healthy lives*" AND "*promoting well-being*". Or if these both were valid, whether that is done "*for all at all ages*". Also, some may have considered in the answer the role of a medical device manufacturer as a supplier to healthcare service providers and therefore chosen to reply "indirectly". Two respondents responded that their company has no impact and one that their company would have an indirect negative impact.

Overall, the responses indicate that the participants possess a critical mindset when it comes to making statements relating to sustainability. This is explained by the fact that the participants have quality and regulatory assurance related roles within their companies; they are accustomed to strict rules of only making claims when sufficient evidence to the claims exists. This as such, increases the credibility of the other answers of the research, as based on this, the participating respondents seem to possess high ethics and low level of social pressure or any other reason to do e.g., so called greenwashing [91], if they are so critical even with regards to this answer.

There were also other SGDs that the participants viewed that their employers contribute with a positive impact. These and possible reasonings are summarized in Table 1. For more details, see Appendix 1.

Table 1: SDGs to which medical device manufacturers based in Finland have a positive contribution, in addition to SGD3 “Good health and well-being”

SDG#	SDG	POSSIBLE REASONING
9	Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation	Medical devices contribute to building resilient healthcare infrastructure through continuous innovation.
4	Ensure inclusive and equitable quality education and promote lifelong learning opportunities for all	Cooperation with universities, equal continuous learning policies within the organization. Industry impacted by continuous changes requiring lifelong learning by all employees.
10	Reduce inequality within and among countries	Sales of medical devices outside of the European Union and North America
12	Ensure sustainable consumption and production patterns	Sustainable manufacturing processes and supplier requirements
5	Achieve gender equality and empower all women and girls	Respondents are located in Finland. Finland is one of the leading countries relating to equality. Organization specific policies and e.g., promotion statistics proving equal treatment and opportunities
8	Promote sustained, inclusive, and sustainable economic growth, full and productive employment, and decent work for all	On a global scale, Finnish society and economy creates a firm basis for this goal
13	Take urgent action to combat climate change and its impacts	Company has included environmental goals into its mission and strategy. Later answers indicate 70% of the respondents agree either fully (30%) or partially (40%) that their company wants to improve environmental sustainability.

Later during the workshop, the participants were asked whether their employer has sustainability embedded in their mission and strategy. All the companies that had sustainability in their mission and strategy, responded that they have a direct positive impact to SDG3. Additionally, these companies declared an indirect positive impact to:

- SDG 9: Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation
- SDG 12: Ensure sustainable consumption and production patterns
- SDG 13: Take urgent action to combat climate change and its impacts.

Siemens Healthineers has identified three core SDGs as goals for them including "good health and well-being" (SDG3), "gender equality" (SDG5), and "responsible consumption and production" (SDG12). [92, p. 17]. Another global medical device manufacturer's Philips' key sustainability commitments include: "good health and well-being" (SDG3), circular economy (SDG12) and climate action (SDG13) [93, p. 45].

Summary: Each company has a unique focus and way of working and that shows in the distribution of the answers relating to impact on United Nation Sustainable Development Goals (UN SDGs). Based on the responses, medical device industry in Finland has the most positive impact at SDG3*: "Good health and well-being" i.e., Ensure healthy lives and promote well-being for all at all ages.*

4.1.2 Impact Assessment Towards SDG3 (Ensure Health and Wellbeing) Targets

After assessing the SDG impacts, the SDG*3: Ensure healthy lives and promote well-being for all at all ages* was opened further on target level as defined by the UN. The participants were asked to assess what impact (positive or negative, direct, or indirect, or none) their employers have on the more specific targets of SDG3.

27 participants completed this section. Due to the generic nature of this question, it was left up to the respondents to evaluate how small of an effect counts as an impact. The results to both the earlier and this assessment are therefore to be considered as qualitative indications, not as quantitative results.

The SDG3 targets to which the responding companies had most direct positive impact included:

- Target 3.d: Strengthen the capacity of all countries, in particular developing countries, for early warning, risk reduction and management of national and global health risks.

- Target 3.1: By 2030, reduce the global maternal mortality ratio to less than 70 per 100,000 live births.

- Target 3.2: By 2030, end preventable deaths of newborns and children under 5 years of age, with all countries aiming to reduce neonatal mortality to at least as low as 12 per 1,000 live births and under 5 mortality to at least as low as 25 per 1,000 live births.

- Target 3.4: By 2030, reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being.

Figure 3 visualizes the number of the direct positive impact answers and how they are divided between the different targets.

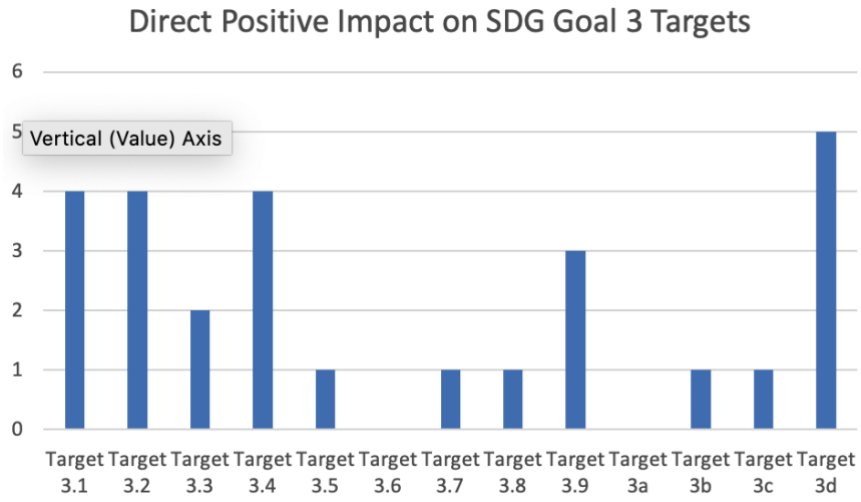

Figure 3: Division of number of direct positive impact answers per SDG3 target

Whereas almost all targets were such that some organizations had direct or indirect positive impact, number-wise most responses were given to “no impact”. For more details, see Appendix 2. The outcome may seem surprising to some, as the answers come from medical device industry. However, solid explanations, provided by the participants themselves, exist.

Participants were asked to review and summarize the outcome of the SDG and SDG3 target related results and provide their views relating to the possible reasons behind. In total, analysis from 17 participants were received. Among them were also input from two participants who had not answered the questions themselves. Table 2 presents the views raised by the participants relating to the SDG and SDG3 target related results.

Table 2: The views raised by the participants relating to the SDG and SDG3 target related results.

REASONINGS	**QUOTES**
Fact that medical devices are designed for very specific use cases	*"Effect depends mostly on the products of the company.", "Medical devices often have very specific uses (for example one disease only).","* The answers and reasons are highly dependent on the area that the company is active in. Medical devices are often very specialized.", "Many of options are non-applicable for specific medical device.", "Direct positive impact on reducing global maternal mortality and fetus mortality" (an example that a specialization may be relating to a specific SDG3 target)
Reaching the SDG3 targets require also access to other essentials beyond access to medical devices	*"(Medical) devices are specific tools for specific procedure. General health relies more on proper availability of clean water, good nutrition, non-violent environment, etc."*
Large global medical device manufacturers have most impact potential	*"Most of us are on specific areas of MD industry, thus can only affect a very small subset of everything.","* More global and bigger companies have more direct positive impact around the world."
Current strategic focus does not cover solving SDG3 targets and this may be due to the estimated financial potential relating to them	*"Most of these don't seem to apply to my business.","* We have not thought about this kind of targets.", "Medical devices are not necessarily targeted for mentioned topics?", "Medical devices are so expensive that some areas suffer from this?", "By providing cost-effective tools for healthcare use, we can make a difference to many things."

The comments are in line with the MedTech Europe statistics relating to medical technology exports from Europe [18, p. 35]: a significant part of exports go to markets that are not the ones with the most significant challenges with the SGD3 targets. (Figure 4)

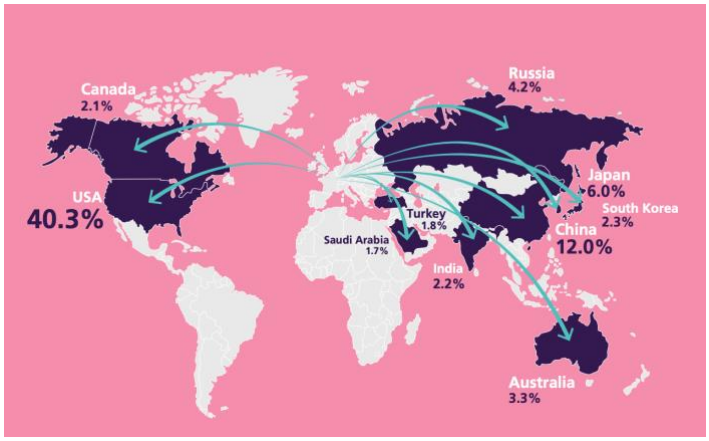

Figure 4: Top European medical technology export destinations 2021. Source: MedTech Europe

According to UN, many of the 46 least developed countries are estimated to double their populations between 2022 and 2050 which sets a challenge to the achievement of SGDs. World population is estimated to reach 8 billion in November 2022 and currently e.g., India's population alone is over 1,4 billion. [94, p. 8] According to medical device market analysts the *"inadequate reimbursement policies"* are responsible for the *"comparatively limited adaptation of medical devices in emerging markets",* combined with the high acquisition price of advanced devices, and components such as chips, batteries and sensors requiring periodic replacement increasing the total cost of ownership [65]. However, potential for change exits. As one member of the Finnish medical device industry summarized it positively: *"By providing cost-effective tools for healthcare use, we can make a difference to many things."*

4.2 STRATEGIC IMPORTANCE AND MANAGEMENT COMMITMENT

Company's vision of future, its mission declaring its purpose, and strategy how it aims to reach the vision direct the operations of the company. Organization's shareholders and board's priorities have direct impact on the priorities of the organization. The following section provides views of the medical device manufacturers based in Finland, relating to strategic importance of sustainability and management's commitment, and how these get manifested e.g., in the set targets, decision-making criteria, and reporting. In each section results are first

presented, followed directly by the related analysis. The figures visually demonstrate the distribution of the number of given responses.

4.2.1 Significance of Sustainability to Customers

Evaluated statement: *"Our customers care about sustainability issues."*

More than half of the respondents (55,17%) agree either fully (6,90%) or partially (48,28%) that their customers care about sustainability issues. Almost a third (31,03%) of the respondents do not know, or do not consider it to be relevant whether their customers care about sustainability issues. Nobody disagrees fully with the given statement, and only 13.79% partially disagree. (Figure 5)

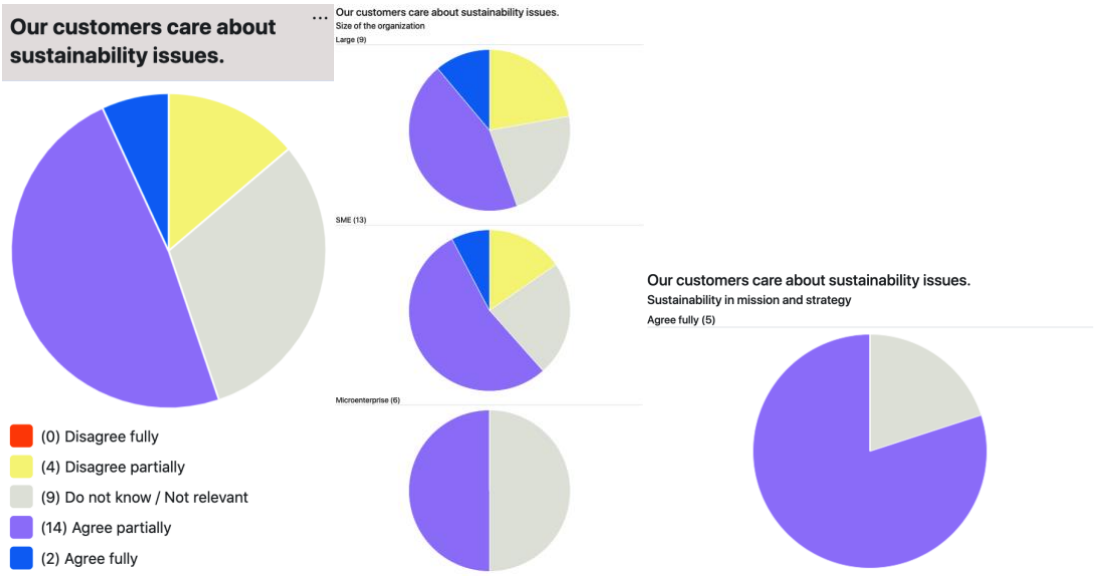

Figure 5: Medical device industry representative's views on whether their company's customers care about sustainability issues. Detailed view of the results based on the company size, and results of companies with sustainability mission and strategy.

No significant differences can be recognized when looking at answers of large and SME sized medical device manufacturers and microenterprises. In practise, the customers are, in many cases the same. The group that has different view are the companies where according to the respondents, sustainability is in the organization's mission and strategy. Most of these companies partially agree with the statement that customers care about sustainability.

What is interesting is that the respondents have predominantly chosen to answer “partially agree” vs. “fully agree” indicating that the sustainability could also, according to them, be potentially even more important to their customers or more clearly communicated by the customers. These responses potentially also refer to patient safety and data security priorities of healthcare service providers. Due to their quality and / or regulatory assurance roles, the respondents may have limited visibility whether the customers care for sustainability issues beyond patient safety and data security. Strict focus on clinical value, safety and security could potentially also explain why 13.79% SMEs and 22,22% of large well established, regulatory compliant medical device manufacturers chose to disagree partially with the given statement.

By nature, some companies are more visionary, driving to transform their industries whereas others are more reactive. For both, financial success is based on the ability to address existing and anticipated needs and priorities of their customers. In 2020, the National Health Service (NHS) in the UK was the world’s first health service to commit to delivering a (carbon) net zero national health service, to fight the *“profound and growing threat to health posed by climate change”* [95] and has since then reported their progress towards the goal. In practise, this commitment included a commitment to work with their suppliers to *“ensure that all of them meet or exceed our commitment to net zero emissions before the end of the decade”* [96, p. 5]. HUS, the largest hospital district in Finland similarly states that *“our strategy stresses responsibility and sustainable development in everything we do”,* and has among other e.g., similar timeline targets for net zero emissions as NHS [97].

Some healthcare service providers will shift their selection criteria towards their suppliers as the regulative requirements will impact them [43]. When Philips interviewed in 2021 3,000 C-suite and senior executive healthcare leaders in 14 countries, 4% of them recognised sustainability to be a key priority at the time, and 58% expected it to be a priority within three years [98, p. 17].

Summary: More than half of the medical device manufacturers based in Finland consider that their customers care about sustainability issues, but that the customers could potentially care about sustainability even more.

4.2.2 Top Management Communication relating to Sustainability

Evaluated statement: *"Our company's top management talks about sustainability."*

Based on the research outcome, the way medical device industry top management communicates about sustainability is divided. Whereas more than half (54,84%) of the respondents say that they agree fully (16,13%) or partially (38,71%) that their management talks about sustainability, almost equal number of respondents exist according to whom their management is not communicating about sustainability or that they are not aware of it (disagree fully 3,23%, disagree partially 29,03%, do not know or not relevant 12,90%). (Figure 6)

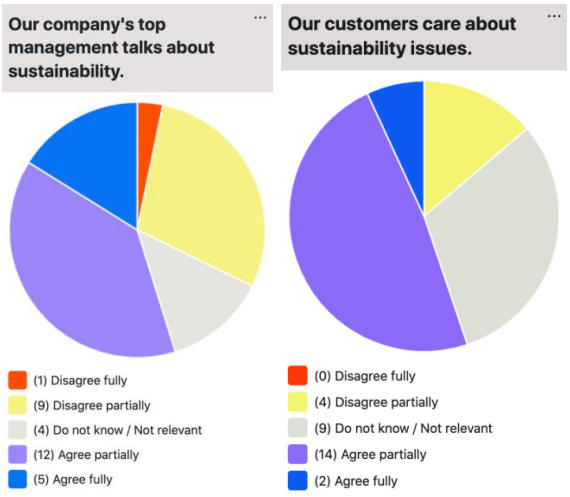

Figure 6: Medical device industry representative's views on top management communication relating to sustainability. Compared with: Medical device industry representative's views on whether their company's customers care about sustainability issues.

More detailed analysis reveals that currently large organizations' top management communicates the most about sustainability, respondents agreeing to the given statement either fully (22,22%) or partially agree (66,67%). SME top management communicates currently less about sustainability (agree fully

13,33% and partially 20,00%). This may be due to considered limited resources and focus on fulfilment of existing strategy and obligations. Interestingly though, about half of microenterprise top management communicates about sustainability (agree fully or partially 50%), so the sustainability related communication is not only linked to the current regulative requirements or the available resources.

The results relating to importance to customers and top managements communication seem to be aligned, indicating that except for large medical device manufacturers that seem to drive the sustainability agenda, no clear push or pull relationship can be identified between healthcare service providers and medical device manufacturers when it comes to communication about sustainability. The fact that of all respondents, only 16,13% agree fully that their top management communicates about sustainability, suggests development potential in this area. In the context of sustainability, the term greenwashing comes up often. When European Commission screened online claims of number of various consumer targeted sectors, in *"37% of cases, the claim included vague and general statements such as "conscious", "eco-friendly", "sustainable" which aimed to convey the unsubstantiated impression to consumers that a product had no negative impact on the environment. Moreover, in 59% of cases the trader had not provided easily accessible evidence to support its claim."* [99] Also, companies with digital products and services supported by AI need to pay careful attention to sustainability related claims [100].

Due to regulative requirements, medical device manufacturers operating in the EU, are used to strong evidence-based communication and therefore have a strong basis to adapt this approach also to sustainability related communication [43]. Evidence based communication about sustainable innovation aspects can have an impact on sales [101].

Summary: About half of top management in the medical device industry talks about sustainability. In large enterprises, sustainability related communication is more common than in small and medium sized companies in the in medical device industry. Relatively low percentage (16.13%) of the "agree fully" answers

indicate demand for increased communication as the sustainability operations increase.

4.2.3 Sustainability as Part of Mission and Strategy

Evaluated statement*: "Sustainability is part of the organization's mission and strategy."*

About a half of respondents (53,33%) agree fully (20%) or partially (33,33%) that sustainability is part of the organization's mission and strategy. In the research further attention is paid to the 20% that fully agree with this statement and these companies are referred to as "Companies with a sustainability mission and strategy".

Even if patient safety and creation of clinical value is at the core of the medical device industry, almost a third of the respondents (32,20%) disagreed fully (3,33%) or partially (28,87%) or did not know (16,67%) that sustainability would be part of the organization's mission and strategy. (Figure 7) This may be due to the respondents' critical mindset and high awareness that sustainability goes beyond creation of clinical value add. This may also explain why a significant part of the companies who did respond positively, chose "partially agree" vs. "fully agree". Closer analysis reveals that 70% of companies that "agree partially" are well established, regulatory compliant medical device manufacturers.

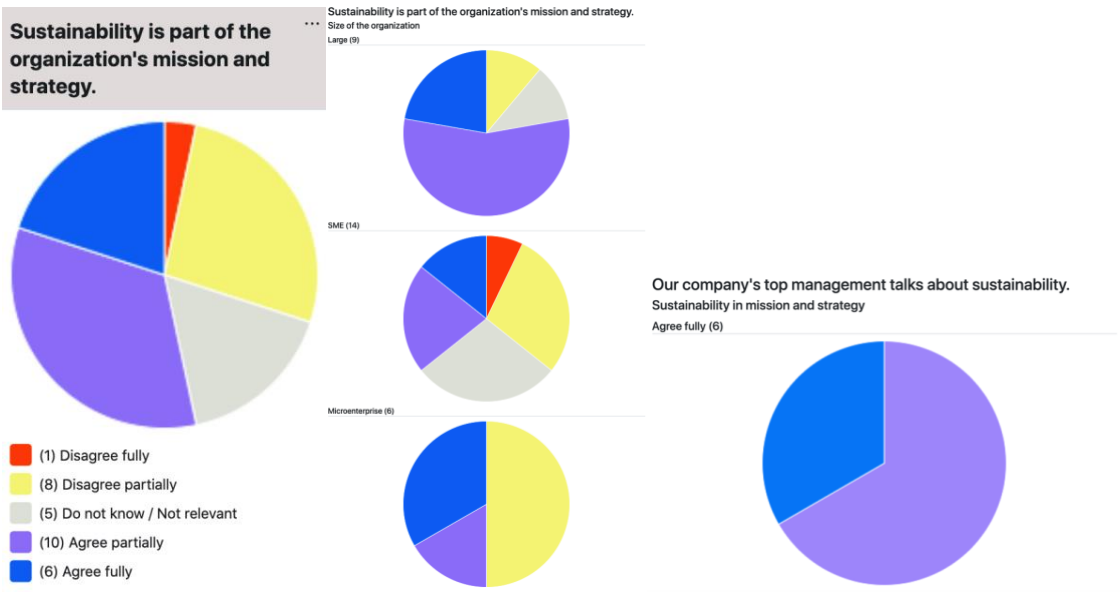

Figure 7: Medical device industry representative's views on whether sustainability is part of company's mission and strategy. Division of results based on the company size. Compared with: Top management communication about sustainability at companies with sustainability mission and strategy.

Company size viewpoint to the question paints an interesting picture: About two thirds of large companies have sustainability in mission and strategy so it can be considered "state of the art" practice for them. Large companies are followed by innovative microenterprises, some of whom may be referred as "born sustainable". SMEs are the group with lowest number of companies with a sustainability mission.

A closer look at the companies that fully agree that sustainability is part of the organization's mission and strategy reveals that these companies' top management communicates about sustainability more than the other companies in the industry. The fact that the companies have sustainability in their mission and strategy provides a solid basis for such communications. Further indication of genuine sustainability communication is that among all companies, regardless of the size, the top management communication relating to strategy seems to be aligned with the mission and strategy. This builds credibility for the sustainability related claims made by the industry.

Mission and strategy have been recognized to contribute for successful implementation of sustainability in practice [102]. According to Sustainability in Finland 2021 research report focusing at large companies, 93% of the researched large companies have included SDGs in the strategy [19] and especially larger companies make their SDG commitments visible. Economic drivers support this development. For example, research over 18-year period suggests that high sustainability companies outperform their counterparts in terms of both stock market and accounting performance [103]. EU's regulative requirements such as the Sustainable Finance Disclosure Regulation (SFDR) [104] has increased investors' interest to understand their investment portfolio's sustainability. This increased investor interest in sustainability impacts companies' missions and strategies.

Serafeim who has extensively researched sustainability and company performance highlights the significance of sustainability being part of the company's purpose and strategy, and advocates that issuing sustainability reports and other standard ESG practises are good business hygiene but what he calls *"window dressing and box checking"* do not contribute to real value generation. Instead Serafeim suggests 1) identification of material issues and development of sustainability initiatives that differentiate the company in the industry 2) ensuring board's commitment to sustainability 3) sharing a common purpose and existence of strong governance 4) decentralizing ESG across the whole organization and 5) regular and transparent communication with investors. [105] Of these particularly, point three is commonly strong at medical device manufacturers.

Summary: Sustainability is to some extent, part of mission and strategy at half of the companies within medical device industry in Finland.

4.2.4 Mission to Operate in a Sustainable Manner

Evaluated statement: *"Our company's mission is to operate in a sustainable manner."*

Whereas the previous statement was given in the beginning of the multiple-choice section of the survey, towards the end of the survey, the participants of the interactive workshop, were asked again whether their company's mission is to operate in a sustainable manner. About 70% (68,97%) of medical device manufacturers based in Finland agreed either fully 20,69% or partially 48,28%. Only a very minor percentage (6,90%) disagreed fully (3,45%) or partially (3,45%), which may be explained through the de facto contribution to health and wellbeing of the industry, as well as regulatory requirement based sophisticated governance models. 24,14% of the respondents did not know or did not find it relevant for their company. (Figure 8)

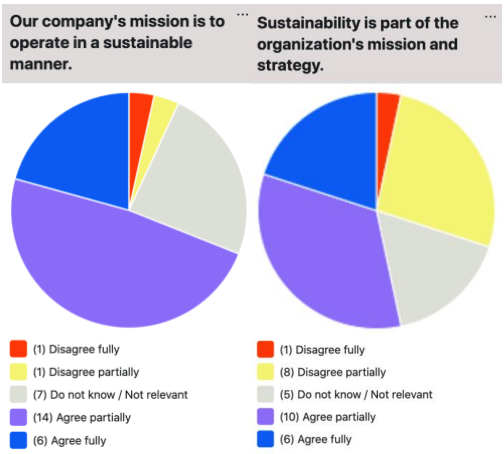

Figure 8: Medical device industry representative's views on whether their company's mission is to operate in a sustainable manner. Compared with: Division of views relating to whether sustainability is part of the organizations' mission and strategy.

The same participants were asked almost the same earlier. Whereas similarity of results increases credibility of the given answers, there were also some differences. Two fine differences in the statements may provide an explanation. The earlier statement included also reference to strategy. The second difference is in the wording: the latter expression "mission is to operate in a sustainable manner" is stronger than "sustainability is part of the organization's mission and strategy". As this is action research aiming to increase awareness and impact the industry members, it can be also speculated, whether spending an hour on sustainability agenda changed the viewpoint of some participants. The slightly different outcomes can also simply be due to non-optimal format of multiple-

choice options. This alternative is possible as a closer analysis reveals that 62,50% of the participants who initially partially disagreed, partially agreed at the end of the interactive workshop. The change may also be due to increased acknowledgement of particularly the social sustainability in the organization's mission. Nevertheless, the results illustrate that about 70% of the medical device manufacturers based in Finland, agree fully or partially that their company's mission is to operate in a sustainable manner.

Summary: Representatives of medical device industry agree fully 20,69% or partially 48,28%, that that their company's mission is to operate in a sustainable manner.

4.2.5 Separate Sustainability Strategy

Evaluated statement*: "There is a separate sustainability strategy."*

A separate sustainability strategy exists only in a minority of companies (agree fully 3,33%, agree partially 13,33%). Substantially large part of respondents responded that they do not know or that the topic is not relevant to them (36,67%). Same amount (36,67%) disagrees fully with the statement that there is a separate sustainability strategy. (Figure 9)

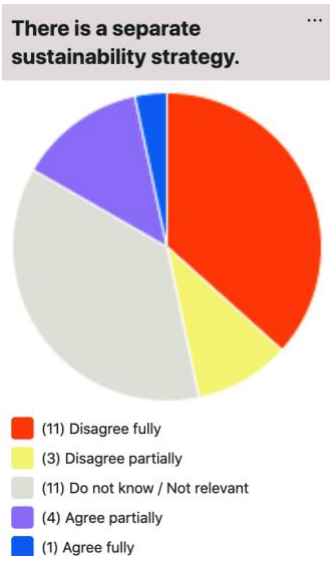

Figure 9: Medical device industry representative's views on whether their companies have a separate sustainability strategy.

Comparing this outcome with the outcome of the previous statements, clarifies that the organizations within the medical device industry who have a strategic approach to sustainability, it is part of the company level strategy, and no separate strategies relating to sustainability exist.

Private sector has a substantial role in society, yet in general, the contribution of businesses towards societal transition towards sustainability has been limited compared to its potential [106]. At the same time many companies in the past have been failing to combine business success with separate sustainability strategies [107]. This has triggered an increasingly popular integrated strategy approach where the company's overall business strategy is closely tied with solving such global sustainability challenges that are relevant to the company. This approach aims to result at both business and societal value [106] [107]. Philips is an example of global medical manufacturer that states that they have *"adopted a fully integrated approach to doing business responsibly and sustainably"* [108].

Summary: Organizations within the medical device industry based in Finland rather have a company level strategy that includes sustainability instead of having a separate sustainability strategy.

4.2.6 Ambition to Improve Environmental, Social and Governance Performance

Evaluated statements: *“Our company wants to improve Environmental sustainability.”, “Our company wants to improve performance on Social factors.”,* and *“Our company wants to improve sustainability related Governance.”*

Results reveal that medical device manufacturers based in Finland have a positive outlook towards improving environmental and social factors as well as governance at their companies. Based on this sample, the interest toward environmental related improvements is the highest 70% (fully agree 30%, partially agree 40%), followed by social 62,06% (fully agree 31,03%, partially agree 31,03%) and governance 48,28% (fully agree 27,59%, partially agree 20,69%). The partially agree responses reflect the ambition level and / or that efforts are not as extensive as they could be according to the standards set by the respondents.

The results indicate furthermore relatively high unawareness relating to ESG improvement ambitions and / or perception that such improvements are not relevant to own work or company. Potential ambitions relating to governance related improvements are most unfamiliar or considered not relevant to the respondents (51,72%), compared to do not know or not relevant answers relating to ambitions on social (37,93%) or environmental (26,67%) related improvements. (Figure 10)

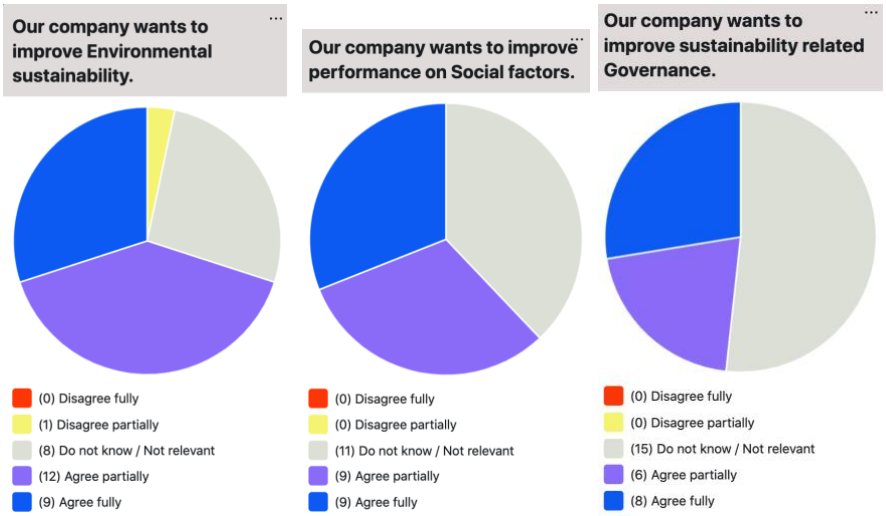

Figure 10: Medical device industry representative's views on whether their company want to improve environmental sustainability, performance on social factors and / or sustainability related governance.

The results leave open what are the reasons behind relatively high percentage of respondents that do not know or think these questions are relevant. One attempt to understand this is by comparing the results with results relating to top management communication and mission and strategy. The results look similar with an interesting difference - whereas some respondents shared that their top management does not communicate about sustainability, and it is not in the mission and strategy - these "anti-sustainability" views do not show in these results. One interpretation is that due to sustainability lacking in the mission, strategy and management communication, the personnel at these companies have concluded that Environmental, Social and Governance (ESG) related improvements are not considered relevant at their company, or they may be unaware whether their company wants to make ESG improvements.

Results also leave open respondents' views relating to current ESG practises and e.g., how satisfied they are on their current governance practises. Based on the industry specific regulative requirements this industry has, by default, very advanced existing governance practises are embedded in the quality management systems that lead all operations. This provides a stable basis for governance improvements and extensions.

A comment by one medical device industry representative participating in the workshop partially conflicts but also complements the multiple-choice answers: *"I think it is a pity that sustainability and especially environmental matters are not often considered very important in medical device industry."* In combination with the above results, the quote may imply that sustainability has recently gained higher priority in the medical device industry.

Summary: The results send a signal that medical device manufacturers based in Finland want to improve their environmental, social and governance performance. At the same time, lack of awareness is identified among some quality and regulatory assurance professionals in this industry relating to how relevant and necessary their company views the need for ESG improvements.

4.2.7 Role of Wider Sustainability Considerations in Decision-making

Evaluated statement: *"Wider sustainability considerations beyond patient safety and data security, are integral part of all decision-making throughout the organization."*

Roughly more than a third of respondents either fully (3,33%) or partially agree (36,67%) that in their company wider sustainability considerations beyond patient safety and data security, are integral part of all decision-making throughout the organization. The fact that the percentage of those who fully agree with the statement is low implies that within the companies that do have wider sustainability considerations in some of their decision-making criteria, it is not a widely applied practice throughout the organization.

At the same time, roughly a third (33,34%) of the respondents either fully disagree (16.67%) or partially disagree (16.67%) with the statement. The latter may indicate that e.g., certain aspects such as employee wellbeing may be handled well in Finland due to legislation and general increased awareness of the connection between employee wellbeing and the work outcome, whereas some other sustainability aspects may not be among the decision criteria.

Remaining respondents (26,67%) do not know or do not consider the matter relevant. (Figure 11) They may know that it is not a decision-making criterion for them but not do not know whether it is elsewhere in the company. Therewith, in this context the “do not know” answers can be perceived as disagreement with the statement. If wider sustainability considerations beyond patient safety and data security were integral part of all decision-making throughout the organization, also quality and regulatory assurance professionals would be aware of it.

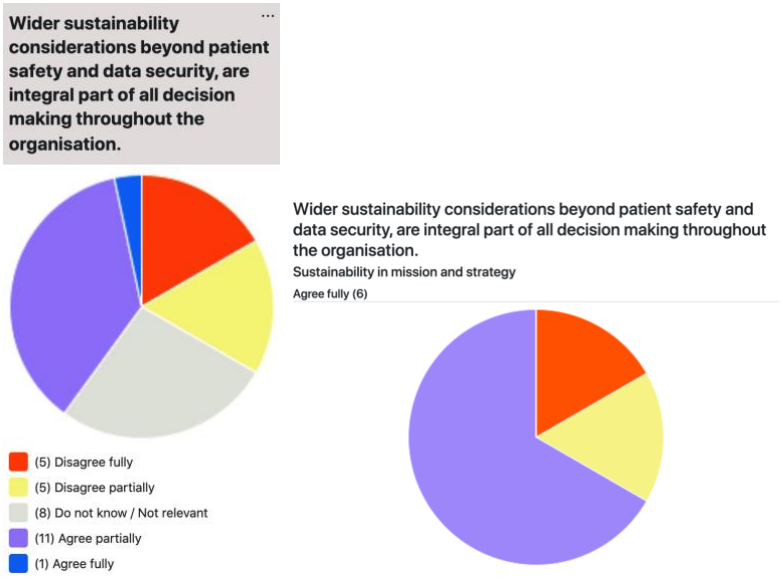

Figure 11: Medical device industry representative’s views on whether wider sustainability considerations beyond patient safety and data security, are integral part of all decision-making throughout the organization. Detailed view of the results at companies with sustainability in mission and strategy.

There were no major differences in the response outcome when analysing the results from the organization size perspective. However, among the companies where sustainability is in the mission and strategy, there seems to be more clarity on whether sustainability considerations are part of decision-making. With nobody fully agreeing, the respondents of that category are painting a picture where also these companies would need to take wider sustainability consideration approach to their decision-making to implement their sustainability driven mission and strategy in practice.

Summary: Wider sustainability considerations that go beyond the patient safety and data security, are currently not an integral part of all decision-making in most of the medical device manufacturers in Finland. About a third of the companies in the industry sample, not fully but partially agree with the given statement, indicating that also in these companies, wider sustainability considerations that go beyond the patient safety and data security, are not a company-wide practice.

4.2.8 Sustainability related Company Level Targets

Evaluated statement: *"Our company has company level sustainability targets."*

Only 6.67% of organizations in the medical device industry has company level sustainability targets (agree fully). At the same time, 13,33% agree partially having such targets, and 63,3% disagree either fully (30%), or partially (33,3%). (Figure 12)

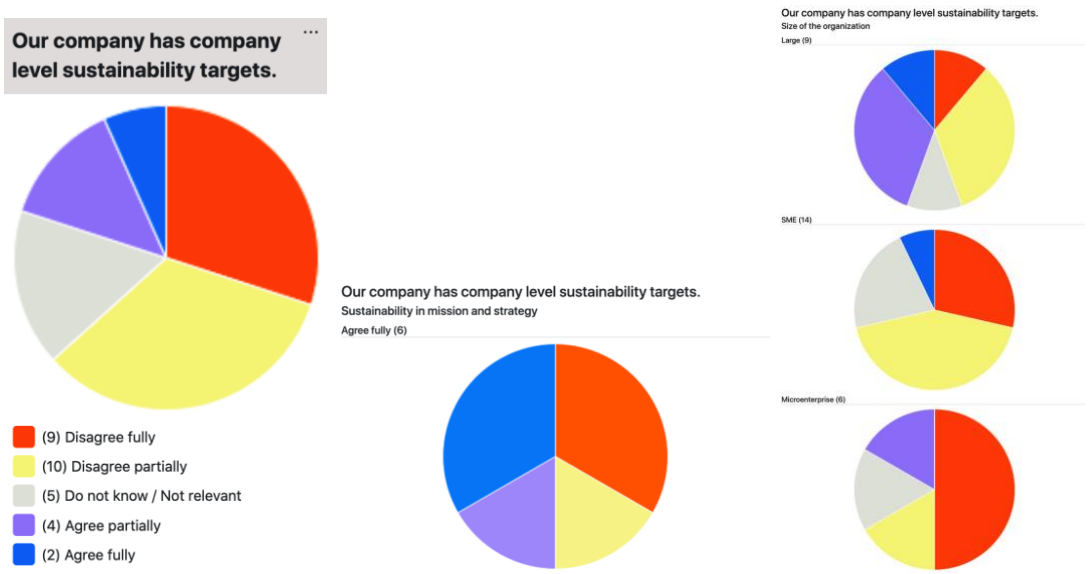

Figure 12: Medical device industry representative's views on whether their companies have company level sustainability targets. Detailed view on the results at companies with sustainability mission Detailed view at the results based on the company size.

It is interesting, that despite about half of the industry having sustainability related mission and strategy, sustainability related targets have not widely materialized in the company level targets. Among companies that have sustainability in their

mission and strategy, only about half have sustainability related company level targets. Large companies in the medical device industry in Finland set more company level sustainability targets than SMEs or microenterprises, but percentage of industry representatives fully agreeing having company level sustainability targets is also relatively low (11,11%) among the large medical device manufacturers. Company level sustainability targets are most common at companies that have sustainability in mission and strategy.

Sustainability target setting requires careful consideration and ideally is focused on real impact whereas e.g., corporate social responsibility activities, and tracking them, cannot be automatically assumed to contribute to social performance improvements [109]. For large companies it is a common practise to link own company level targets such as carbon reduction targets to external targets, Paris Agreement being most common external reference point [73, p. 43].

Summary: Despite half of the industry having sustainability related mission and strategy, it has not yet led to wide materialization of company level sustainability targets at medical device manufacturers based in Finland.

4.2.9 Ambitions for Medical Devices to Qualify as Environmentally Sustainable

Evaluated statement: *“Our company aims to have a certain % of medical devices qualify as environmentally sustainable.”*

About three quarters (72,41%) of respondents do not know or find it relevant whether their company aims to have certain % of their products qualify as environmentally sustainable. At the same time, 10,34% partially agree with the given statement, whereas 17,24% disagree either fully 6,90% or partially 10,34%. (Figure 13)

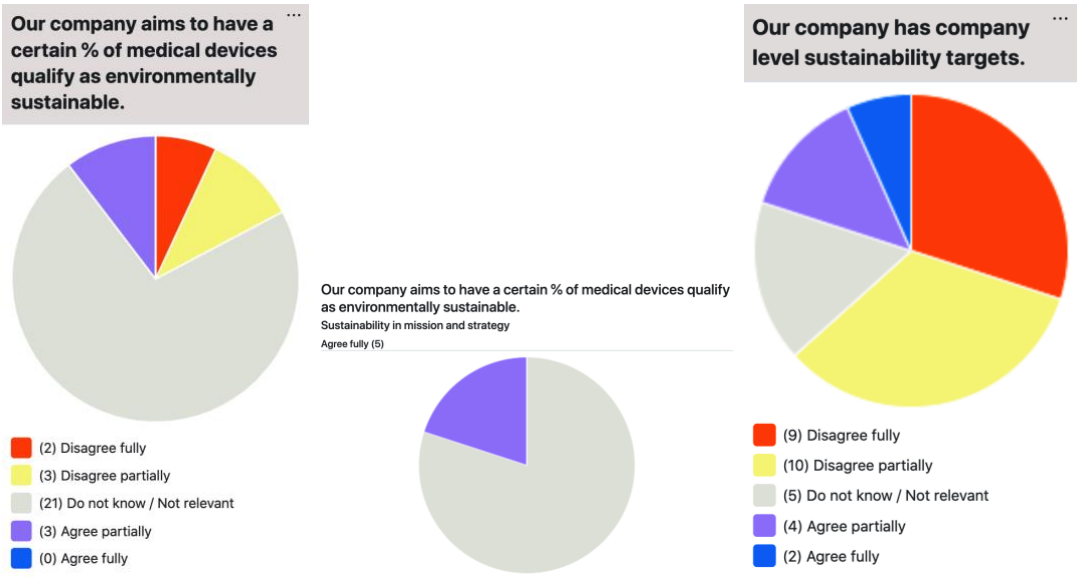

Figure 13: Medical device industry representative's views on whether their company aims to have a certain percentage of medical devices qualify as environmentally sustainable. Detailed view of the results at companies with sustainability mission and strategy. Compared with: Division of views on whether the company has company level sustainability targets.

What is clear about the results that such ambitions are currently not among the widely known targets of the medical device manufacturers based in Finland. Whereas almost 20% of respondents know that such ambitions do not exist, the vast majority, about 70% (72,41%) of the respondents responded, "do not know or not relevant". Earlier answers indicated that close to 70% companies want to improve environmental sustainability, therefore it seems probable that "do not know" would be more applicable to those companies than "not relevant". At the same time, it is worth remembering that up to 30% of the respondents indicated that their mission and strategy does not include sustainability, so they may, based on that, consider that suggested targets are not relevant for them. Similarly, respondents who shared that their company does not have sustainability related company level targets may also have concluded that suggested more specific targets are not relevant for them.

The overall industry agnostic trend is clear as EU wants to make sustainable products the norm in the EU [110]. Whereas medical device industry is well familiar with the *"Primum non nocere - First do no harm"* principle, the EU taxonomy has introduced environmental objectives defining what can be

considered as environmentally sustainable economic activities, and related *"Do not significant harm"* principle. According to the principle no measure should lead to significant harm of any of the six environmental objectives including 1) climate change mitigation, 2) climate change adaptation, 3) sustainable use and protection of water and marine resources, 4) circular economy, 5) pollution prevention and control, and 6) protection and restoration of biodiversity and ecosystems [111]. As EU's regulatory requirements push investors to report about sustainability of their portfolio, that will indirectly impact also medical device industry [104].

Summary: Quality and regulatory assurance professionals at medical device manufacturers based in Finland are not currently aware or find it relevant that their companies would set goals aiming to have a certain percentage of medical devices qualify as environmentally sustainable.

4.2.10 Ambitions for Environmentally Sustainable Procurement

Evaluated statement: *"Our company aims to have a certain % of purchases environmentally sustainable."*

Majority of the respondents (72,41 %) do not know or consider it to be relevant whether their company aims to have a certain percentage of purchases environmentally sustainable. Only 10,34% of respondents agree fully (3,45%) or partially (6,90%) and 17,24% respondents disagree fully (3,45%) or partially 13.79%. (Figure 14)

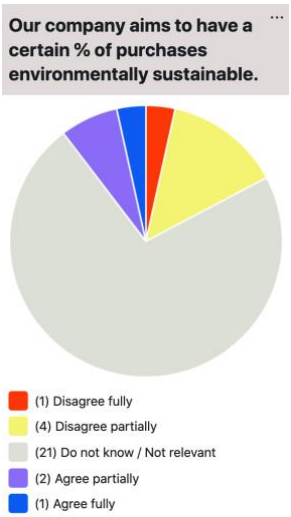

Figure 14: Medical device industry representative's views on whether their company aims to have a certain percentage of purchases environmentally sustainable is systematically monitored.

The results form a picture where medical device manufacturers based in Finland currently do not set percentage related targets for environmentally sustainable purchases. Compared to many other industries, this industry has a particular reasoning: their priorities are tied to securing patient and user safety, also when it comes to e.g., material selection. However, environmental targets do not have to be contradicting with the patient safety targets. Incentivizing suppliers to adopt and meet Science Based Targets (SBT) [70] have been estimated have seven times larger impact than the reduction of CO_2 emissions of a medical device manufacturer's own operations only [112].

Medical device manufacturers have established processes and quality agreements to monitor supplier performance, so both the supplier and the medical device organization are already accustomed to e.g., conducting performance reviews [113].

Summary:

Majority of the respondents (72,41 %) do not know or consider relevant whether their company aims to have a certain percentage of purchases environmentally sustainable.

4.2.11 Production of Sustainability Reporting

Evaluated statement: *"Company produces sustainability reporting."*

Less than 20% of the medical device industry players currently produce sustainability reporting (12,9% fully agree or 6,45% partially agree). Over half (54,84%) of the respondents disagree either fully (45,16%) or partially (9,68%), whereas 25,81% do not know or do not find producing of sustainability reporting relevant for their company. (Figure 15)

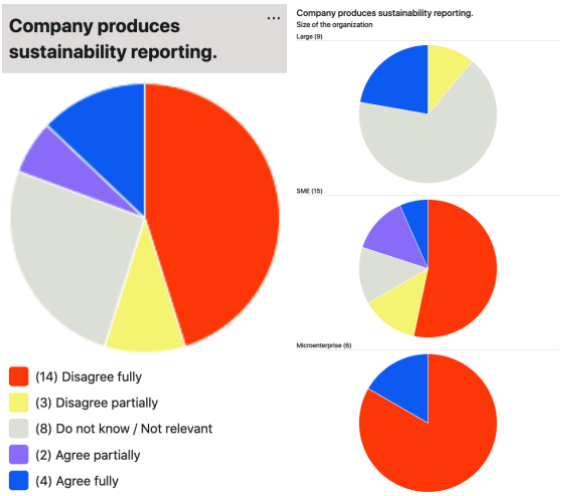

Figure 15: Medical device industry representative's views on whether their company produces sustainability reporting. Detailed view at the results based on the company size.

Current EU regulative requirements require the largest companies to publish such reporting [42]. The outcome of the research reveals existence of sustainability aware SMEs and microenterprises that produce sustainability reporting.

The results of the survey demonstrate the fact that in large companies, employees are not necessarily aware of the existence of sustainability reporting. Thus, the sustainability reporting is not closely linked to daily operations of quality and regulatory assurance professionals and / or the contents of sustainability reports are not discussed in the similar way that e.g., the contents of the financial reports. Similarly, the results indicate that the smaller the company the better the people are aware what reporting is conducted and what not. The results indicate

that even small companies can choose to monitor the execution of its strategy with sustainability reporting.

Proposed future EU sustainability reporting regulations aim to position sustainability reporting on a parallel level with financial reporting as part of annual reports, making the top management directly accountable for the contents [43]. The future reporting requirements of large and stock listed companies are also expected to impact smaller companies which operate as suppliers to such companies [114].

Despite the wider healthcare industry moving towards increased data driven operations and decision making, data relating to sustainability of medical device manufacturer in form of sustainability reporting is still limited.

Summary: Only a small portion (less than 20%) of the medical device industry actors currently produce sustainability reporting.

4.3 SUSTAINABILITY OF OPERATIONS

This section aims to increase understanding relating to the level sustainability has been integrated to the operations at the researched medical device manufacturers based in Finland.

4.3.1 QMS References to Sustainability or Sustainability Factors

Evaluated statement: *"Our QMS includes references to sustainability / sustainability factors."*

Majority of the research participants disagree fully (30%) or partially (30%) with the statement that the Quality Management System (QMS) of their company includes references to sustainability or sustainability factors. Close to 30% (27,59%) do not know or do not find this information to be relevant. Only a very small part of organizations participating the research fully agree (3,33%) or

partially agree (13,33%) that their QMS includes references to sustainability or sustainability factors. (Figure 16)

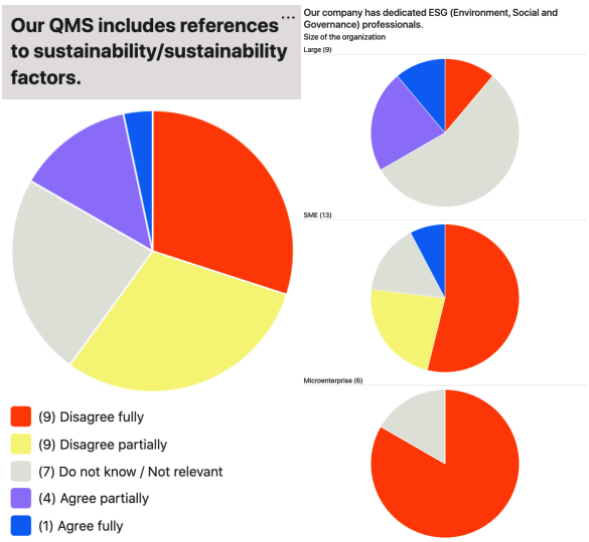

Figure 16: Medical device industry representative's views on whether their company's QMS includes references to sustainability/sustainability factors. Detailed view of the results based on the company size.

No common nominator can be found for the medical device manufacturers which fully or partially agree with the statement, based on e.g., their size, headquarter location or customer location. But respondents that fully or partially agree that their QMS includes references to sustainability or sustainability factors also fully or partially agree that sustainability is part of their company's mission and strategy, and are all well-established, regulatory compliant medical device manufacturers.

What is interesting is that the portion of the "do not know or not relevant" answers is highest at the large medical device manufacturers. At smaller companies, the respondents, quality and regulatory assurance professionals, know with higher certainty that sustainability or sustainability factors are not included in the QMS.

Quality Management System of a manufacturer defines the processes and other requirements set for an organization to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable

regulatory requirements [113]. By nature, QMS is comprehensive and as the industry saying goes *"if something is not documented in the QMS, it does not exist".*

Summary: At majority (62,07%) of the researched organizations, the Quality Management System does not include references to sustainability or sustainability factors.

4.3.2 Inclusion of Sustainability related Targets to Operational Quality Metrics

Evaluated statement: *"Our operational quality metrics include sustainability related targets."*

The results are well aligned with the previous QMS related statement - same respondents that fully or partially agreed that their QMS has references to sustainability or sustainability factors, also fully (3,33%) or partially agree (13,34%) that their quality metrics include sustainability related targets. The respondents of "do not know or not relevant" option (36,67%) follow the same logic. (Figure 17)

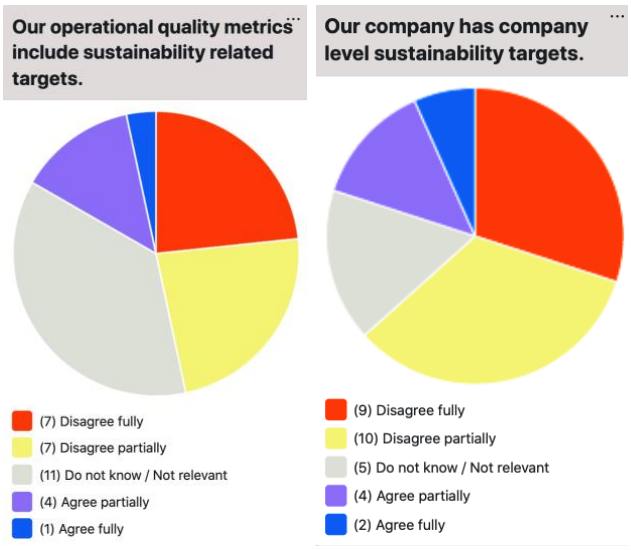

Figure 17: Medical device industry representative's views on whether their company's operational quality metrics include sustainability related targets. Compared with: Medical device industry representative's views on whether their company has company level sustainability targets.

The alignment with the QMS related answers adds credibility to both answers. Similar alignment can be found when comparing the answers with the company level sustainability targets. Main difference is that the respondents are more aware of potential existence of the company level targets versus existence of more precise sustainability related quality metrics. This is slightly surprising as the respondents work in quality and regulatory assurance roles and therefore awareness of the contents of the quality metrics relates to their work. On a higher level the results indicate that sustainability related targets do not seem to be perceived to be closely linked to quality.

The chosen metrics reflect the company priorities and performance. Based on ISO 13485, medical device manufacturers need to conduct systematic monitoring, measuring, analysis and improvement to *"demonstrate conformity of the product and QMS, and maintain the effectiveness of the QMS"* [113]. The standard calls for usage of appropriate methods and metrics for systematic monitoring and measuring to demonstrate continuous conformity and effectiveness. Multi-year aspirational goals, typical for sustainable development, are not therefore explicitly encouraged by the standard. However, e.g., at Siemens Healthineers quality objectives are long-term targets derived from the strategy. Individual units of the company base their measurable quality objectives in their QMS based on these long-term targets [92, p. 87].

Summary: A small minority (16,66%) of medical device manufacturers based in Finland include sustainability related targets in their quality metrics.

4.3.3 Sustainability related Product Requirements

Evaluated statement: "*Our product requirements include sustainability related requirements."*

The answers related to the statement get strongly divided to two differing views: About half of respondent disagree fully (23,33%) or partially (26,67%) and on the other hand a large part of respondents agree partially (36,67%) or fully (3,33%). (Figure 18)

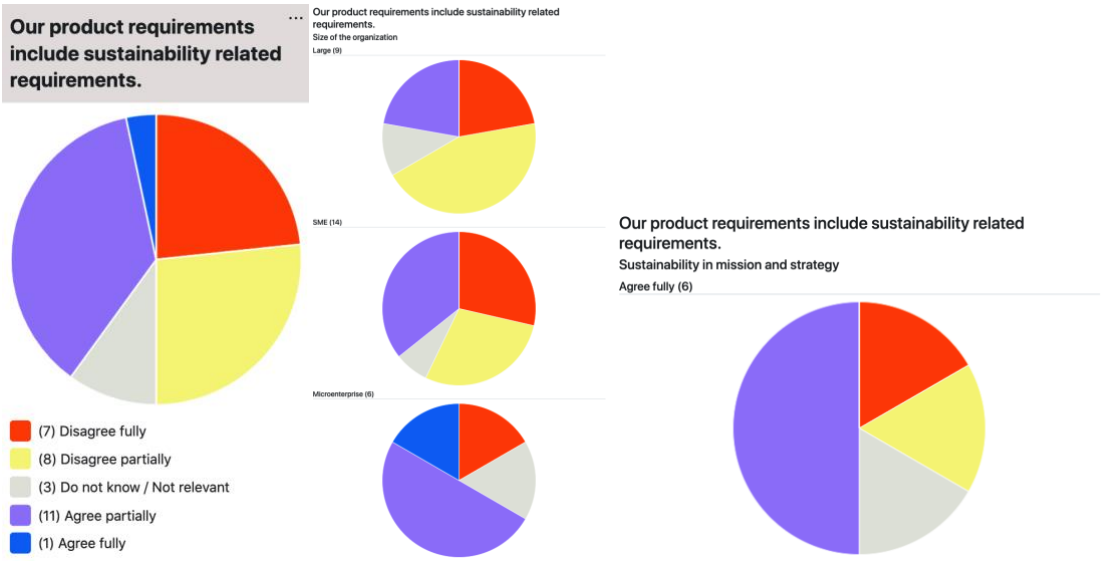

Figure 18: Medical device industry representative's views on whether their product requirements include sustainability related requirements. Detailed view of the results based on the company size. Detailed view of the results at companies with sustainability mission.

The fact that about 40% of respondents partially or fully consider that their product requirements include sustainability related requirements may be due to the medical device requirements relating to patient, professional user and healthcare industry value add. The total view, the fact that only a marginal 3,33% of respondents fully agree with the given statement and so large part disagrees or is not aware or conditionally agrees, implies that the representatives of medical device manufacturers based in Finland do not consider that sustainability, beyond the current industry specific requirements, is currently taken into consideration at the product requirement stage.

The company size perspective to this question is interesting as it shows that microenterprises are leaders when it comes to sustainability related product requirements. More surprising is, however, that based on the given answers, about two thirds of large companies do not have sustainability related product requirements, while at the same time, as indicated earlier two thirds of the same large companies have sustainability in their mission and strategy.

Comparison of the product requirement results with the statement relating to significance of sustainability to customers, hints that the customers of medical

device manufacturers could appreciate even wider set of sustainability related product requirements.

Product requirements are the input for medical device design and development; what is included in the product requirements, gets designed and developed. Similarly, medical devices' quality and performance is validated and verified against the different level of requirements set for the product. [113]

For example, requirements relating to physical or digital size and features of the product, electricity consumption, human resources, materials, suppliers, packaging, transportation, refurbishment, and recycling impact the product sustainability. As the role of software in medical devices increases, also the cloud service provider's sustainability has a large impact. In general, awareness and interest for green ICT has increased recently in Finland [115].

Summary: Patient safety and data security are in the core of medical device requirements, and they can be considered sustainability requirements. Partial agreements and disagreement indicate potential for growth in this area. Also, almost a quarter (23,33%) of all respondents fully disagree that product requirements include sustainability related requirements.

4.3.4 Consideration of Sustainability Factors in the Device Design Process

Evaluated statement: "*Sustainability factors are considered in the medical device design process e.g., by using ecodesign principles."*

The results reveal that about 45% (44,83%) of respondents do not know whether sustainability factors are considered in the medical device design process. Similarly, about 45% of respondents disagree fully (13,79%) or partially (31,03%) with the given statement. None of the respondents fully agree with the given statement and only 10,34% partially agree. (Figure 19)

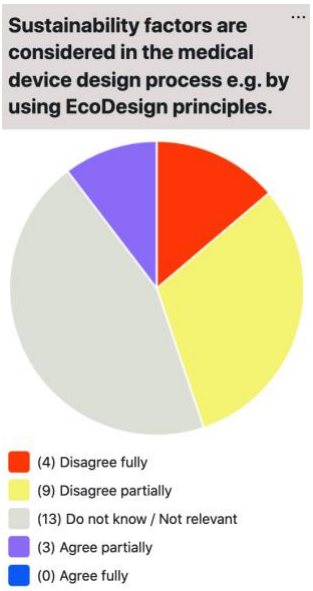

Figure 19: Medical device industry representative's views on whether sustainability factors are considered in the medical device design process e.g., by using ecodesign principles.

Whereas the previous statement focused on the sustainability related product requirements, this statement was relating to the medical device design process i.e., how the product design process is conducted. Partial disagreements may relate to a situation where current regulatory requirement-based aspects are complied with, but principles such as ecodesign are not in use. Respondents have quality and regulatory assurance roles at their organizations so they do not directly work according to these processes but on high level they should be aware of the principles used.

Whereas EU's original ecodesign regulations date back to 2009, a sector agnostic Proposal for Regulation on Ecodesign for Sustainable products was adapted in March 2022. According to the proposal "*'Ecodesign' means the integration of environmental sustainability considerations into the characteristics of a product and the processes taking place throughout the product's value chain. 'Product' means any physical good that is placed on the market or put into the service."* [39]

Ecodesign principle is used e.g., at Philips, and the company targets that all new products would be ecodesigned by 2025. Their 2021 annual report contains the

elements of the company level environmental impact, and accordingly 80% of the total environmental impact takes place in customer use phase (€1,74 billion of the total impact of €2,14 billion). [93, p. 49] This is interesting in combination with European Commission' quote on a generic estimation that 80% of all product-related environmental impacts are determined at the product's design phase [116].

Medical device design is generally focused on functionality, performance, usability, and safety-based risk management. ISO 13485 design and development inputs also include option for *"other requirements essential for design and development of the product and processes"* [113]. Could the design input requirements in the future, more increasingly relate to enabling sustainable usage and behaviour?

Summary: Sustainability factors are predominantly not considered in the medical device design process (e.g., by using ecodesign principles) at medical device manufacturers based in Finland. Only 10,34% of the respondents partially agree that sustainability factors are considered in their medical device design process e.g., by using ecodesign principles.

4.3.5 Sustainability as Supplier Selection and Monitoring Criteria

Evaluated statement: "*Supplier's sustainability is a selection criterion and ESG performance is systematically monitored."*

Less than a quarter of the respondents (24,14%) agree fully (3,45%) or partially (20,69%) that suppliers' sustainability is a selection criterion and how the supplier performs against ESG targets is systematically monitored. About a third of respondents (34,49% disagree fully (24,14%) or partially (10,35%) with the given statement. (Figure 20)

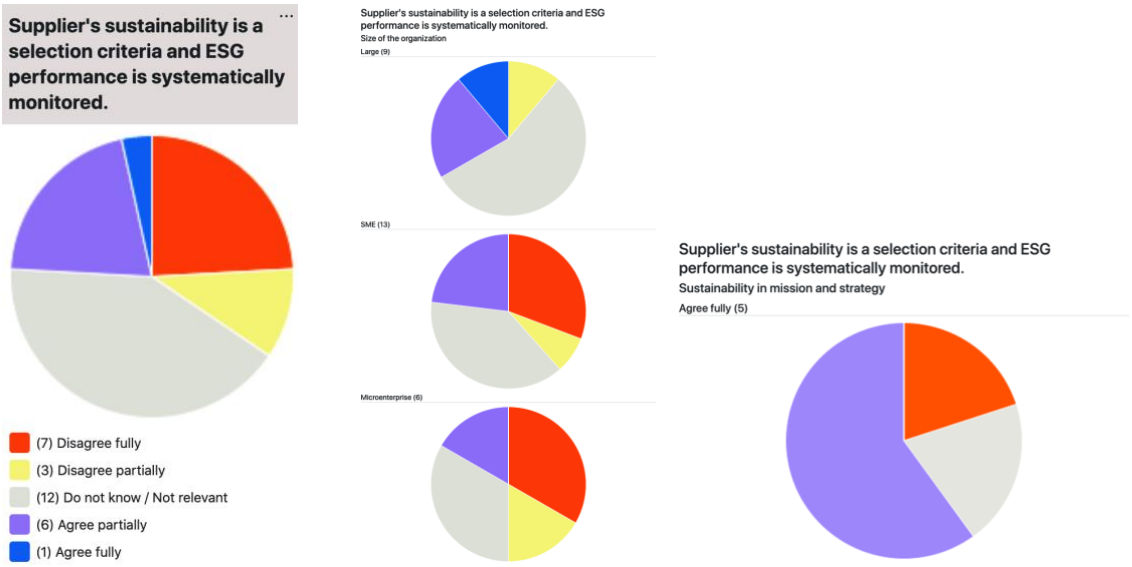

Figure 20: Medical device industry representative's views on whether suppliers' sustainability is a selection criterion and suppliers' ESG performance is systematically monitored. Detailed view of the results based on the company size. Detailed view of the results at companies with sustainability mission and strategy.

What stands out is that such large part of the respondents (41,38%) do not know or do not consider this to be relevant, particularly considering that most respondents have quality and / or regulative assurance role within a medical device manufacturer. In general terms, people in charge of quality and regulatory compliancy should be aware of high-level requirements set for the suppliers of medical device manufacturers. The level of unawareness is highest at the large organizations. That reflects the level of communication between departments, and the level in which sustainability is embedded into the company values.

Setting sustainability related requirements for the suppliers is higher than the industry average among the companies that have sustainability in their mission and strategy. It is to be noticed that the respondents in this category still only partially agree with the given statement, indicating that in their view further improvements to the current situation would be possible.

Having an understanding, of the significance suppliers have on the total sustainability [112], creates a good basis for meeting future regulative

requirements requiring addressing sustainability from a whole value chain perspective [43]. Taking value chain level responsibility for patient safety is already familiar for the medical device manufacturers [10].

It is to be expected that customers of medical device manufacturers will have increasing interest in alignment of sustainability targets across the supply chain [68]. HUS, the largest hospital district in Finland, has set sustainable procurement guidelines and is systematically tracking the sustainability of its logistics and supply chain. Procurement decision of medical devices is impacted by the initial acquisition costs, and the lifecycle cost estimation. [117, p. 13]

Summary: Suppliers' sustainability is not yet an industry-wide common selection criterion and the sustainability of medical device manufacturers suppliers are not monitored systematically. With only 3,45% of medical device industry representatives stating that supplier's sustainability is a selection criterion and suppliers ESG performance is systematically monitored, about a quarter of respondents (24,14%) partially agree with that, reflecting further development potential in this area.

4.3.6 Sustainability as a Distributor Selection and Monitoring Criteria

Evaluated statement: "*Distributors' and partners' sustainability is a selection criterion and ESG performance is systematically monitored."*

The results relating to the distributor and partner sustainability statement look practically the same as the results relating to the suppliers. 43,33 % of the respondents do not know or find the topic relevant. A third of the respondents (33,33%) disagree fully (23,33%) or partially (10%), 23,33% agree fully (3,33%) or partially (20%) with the given statement. (Figure 21)

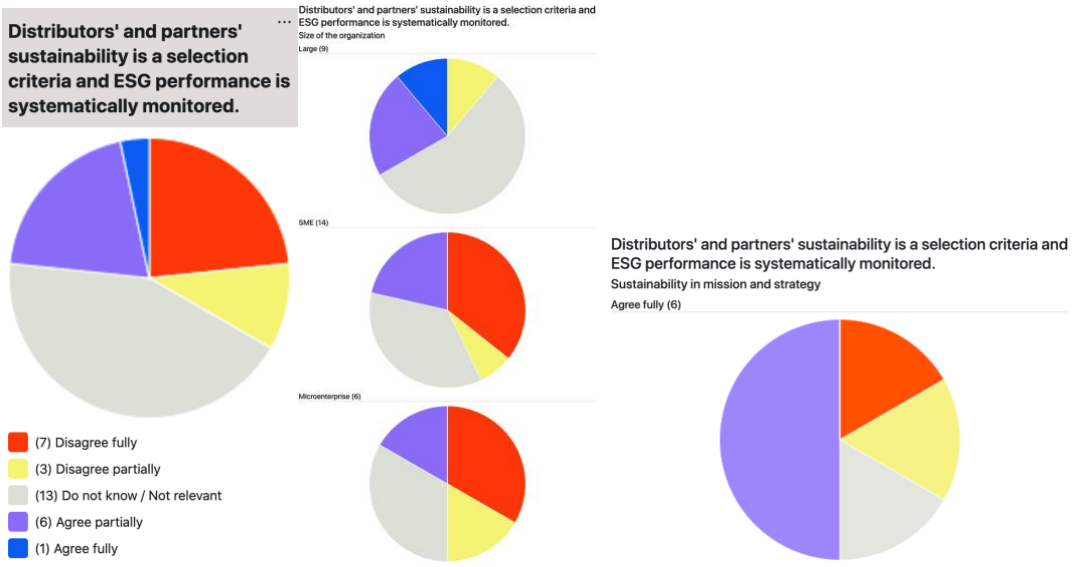

Figure 21: Medical device industry representatives' views on whether their distributors' and partners' sustainability is a selection criterion and distributors' and their ESG performance is systematically monitored. Detailed view of the results based on the companies with sustainability mission and strategy.

Analysis reveals that companies that have extended sustainability requirements outside of their immediate own organization, have taken both directions of the value chain into consideration. Amount of "Do not know or not relevant" answers is significant and highest at large organizations. Unawareness whether sustainability of distributors and partners is a priority, can partially be explained by the roles of the respondents; quality and regulatory assurance professionals at medical device industry possess a particularly high ethics and moral, they do not guess, but by default, are typically prepared to provide the supporting evidence to their views.

At companies where sustainability is in the mission and strategy, the results resemble their supplier related results, implying development potential in this area. In general, due to low level of "fully agree" responses, it can be concluded that at the medical device industry in Finland, the primary sustainability related efforts are focused on the company's own activities and that the requirements for third parties that go beyond the current regulative requirements relating to patient safety and data security, are not widely applied. Would they be applied it can be assumed that there would also be higher level of awareness of that.

Medical Device Regulation sets requirements for supplier and distributor selection as well as monitoring and existence of such processes [10]. This forms a strong basis for the ability to deploy the current frameworks in case of new supplier and distributor requirements.

Summary: The results resemble the results relating to supplier selection and monitoring. About 40% (43,33 %) of the respondents do not know or find the topic relevant. At most organizations in the medical device industry in Finland, for the time being, the focus of sustainability activities is at own operations, with less or no focus at sustainability of distributors and partners.

4.3.7 Usage of Life-Cycle Assessment (LCA) Tool

Evaluated statement: "*Company uses a Life-Cycle Assessment (LCA) tool to assess the environmental impact of its operations."*

Currently, within the medical device industry in Finland, only a very small part (13,8%) uses a Life-Cycle Assessment (LCA) tool to assess the environmental impact of its operations (agree fully 3,45%, agree partially 10,35%). About half of the respondents disagree either fully (37,93%) or partially (10,35%) with the given statement. Almost 40% (37,94%) do not know whether LCA is used or consider the theme irrelevant for them or their company. (Figure 22)

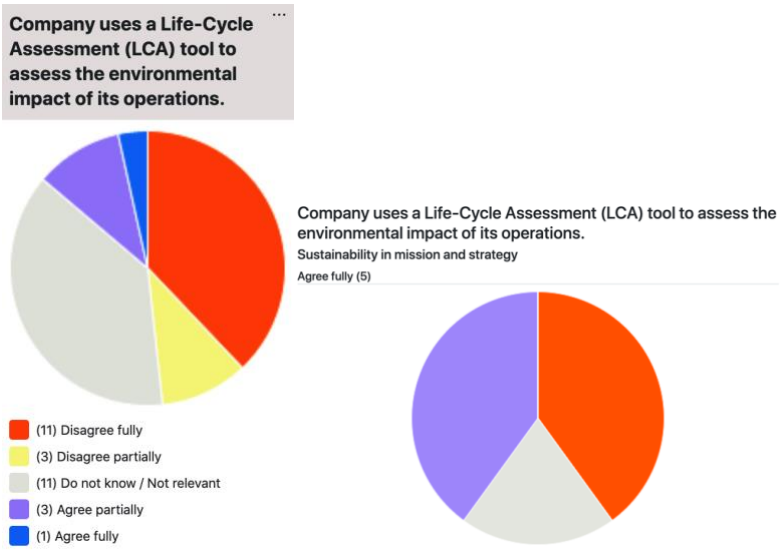

Figure 22: Medical device industry representative's views on whether their company uses a Life-Cycle Assessment (LCA) tool to assess the environmental impact of its operations. Detailed view of the results at companies with sustainability mission and strategy.

The results reflect that if LCA is used within these organisations, it is not a topic that is widely communicated or discussed within the organizations, or that environmental Life-Cycle Assessments are not considered relevant. Even if LCA tools are more widely used, at medical device manufacturers who have sustainability in their mission and strategy, it is not a widely used practise in these companies either. The companies that use LCA are either large or SME sized medical device manufacturers that have in addition to the EU also customers in North America and / or elsewhere.

ISO 14040 and ISO 14044 based Life-Cycle Assessments are used to assess impact of products and processes in multiple industries over the entire lifecycle [118] [119]. Understanding of the environmental impact of current operations and products forms a basis to be able to focus attention at areas that make the most significant impact. Life cycle thinking is not a new concept but have been referred to in EU policies for three decades already, resulting at different adaptation levels at different sectors [120]. At the end of 2020, Sousa el al. researched usage of Life Cycle Assessment (LCA) and ecodesign at medical device manufacturers and concluded that despite positive impact on environmental sustainability of medical devices, the amount of scientific literature relating to use of LCA and

ecodesign is still limited [81]. Philips utilizes LCA and has commercialized related services [121].

Summary: Life-Cycle Assessment (LCA) is not a commonly used approach within the respondent companies. Only a small minority (13,8%) uses a LCA tool to assess the environmental impact of its operations.

4.3.8 Medical Device Re-cycling

Evaluated statement: *"Our company takes care of the medical device re-cycling."*

About half of respondents agree either fully (22,58%) or partially (25,81%) that their company takes care of the medical device re-cycling. Quite a large part of respondents (38,71%) does not know or does not consider this to be relevant, whereas 12,90% disagree fully (9,68%) or partially (3,23%). (Figure 23)

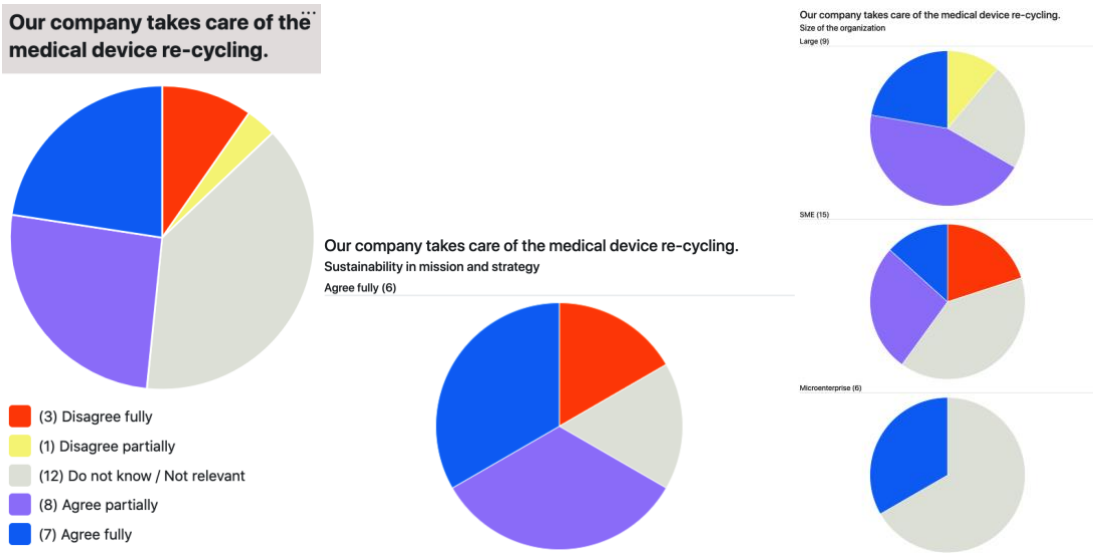

Figure 23: Medical device industry representative's views on whether their company takes care of medical device re-cycling. Detailed view of the results at companies where sustainability is part of mission and strategy. Detailed view of the results based on the company size.

The fact that relatively so many medical device manufacturers chose the alternative "do not know or not relevant", may be due to the two different answer

options been grouped together. Some respondents might indeed not know which reflects low level of communication and / or low priority in the organization. Another, maybe more relevant explanation is that some medical devices are software based only, with no need to recycle the physical medical device. This can also be reason for some of the disagreement answers. Among the medical device manufacturers that have sustainability in mission and strategy, the situation is slightly more advanced, but also among these responses “disagree fully” and “do not know or not relevant” answers can be found.

Awareness of the device recycling level is highest at the large manufacturers, as well as the actual level of recycling. This implies that quality and regulatory assurance professionals at large manufacturers are aware of sustainability activities even if they would not directly contribute to them. Considering that large manufacturers have the largest global market share, the results in one hand look positive. On the other hand, as less than a quarter of the respondents fully agree, the results suggest development potential in this area.

When analysing these figures, it is important to keep in mind that they provide a high-level indication only relating to whether recycling is conducted at all or not. What the statistics do not reveal is the bandwidth of the circular operations. For example, Philips reported that in 2021, 16% of their revenues were from circular propositions and in 2015 the same percentage was 7% [93, p. 250]. This indicates that despite of deliberate actions, the transition of a medical device manufacturer to circular operations requires time.

Summary: About a half of the medical device manufacturers based in Finland re-cycle medical devices.

4.3.9 Perceived Sufficiency of Current Sustainability Efforts

Evaluated statement: *“Our company's sustainability efforts are considered to be sufficient.”*

40% of the respondents perceive that the current sustainability efforts of the company are considered sufficient, however only 6,67% agree fully. This demonstrates the understanding within medical device industry in Finland that despite the current efforts, demand for further actions relating to sustainability exist.

A third of the respondents (33,33%) disagree partially, meaning that according to them the company's sustainability efforts are not considered to be sufficient. No respondent disagrees fully. (Figure 24) This may be due to majority of the respondents being regulatory compliant medical device manufacturers, who get scrutinized in annual audits for compliance with the industry specific regulations and standards.

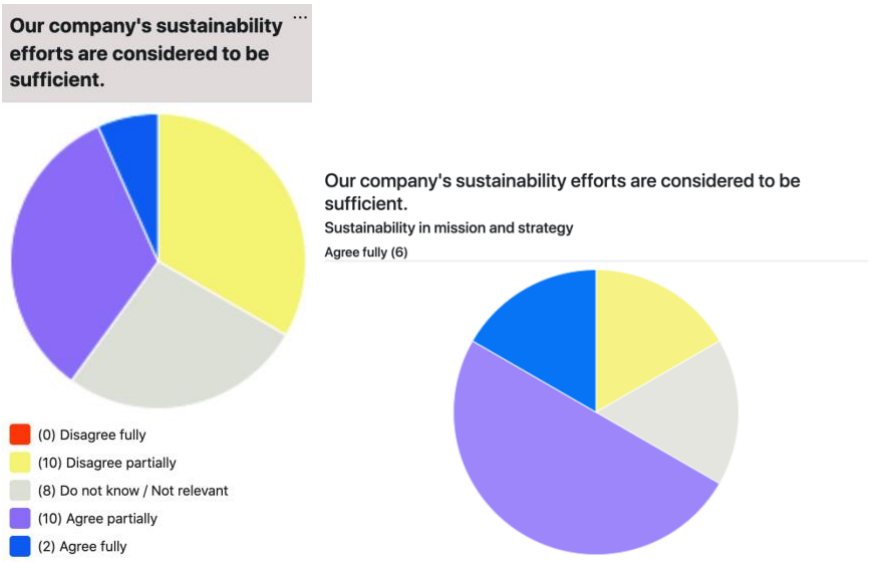

Figure 24: Medical device industry representative's views on whether their company's sustainability efforts are considered sufficient. Detailed view at the results at companies with sustainability mission.

Companies that have sustainability in mission and strategy have higher level of confidence in the sufficiency of their efforts. However, on the other hand, also in this group, only a small minority (16,6%) fully agrees that the efforts would be sufficient. This demonstrates wider understanding of the scope of various potential sustainability efforts and the level or real impact created [109].

Summary: With only a small minority (6,67%) fully agreeing with the given statement, members of the medical device industry perceive that the current sustainability efforts are not as sufficient as they could be.

4.4 SUSTAINABILITY RELATED RISK MANAGEMENT

Risk management is an overarching principle in medical device manufacturers operations. This section investigates sustainability related risk management at medical device manufacturers based in Finland.

4.4.1 Status of Sustainability Risk Management

Question: *"How are the sustainability risks managed at your company currently?"*

The workshop participants included quality and regulative requirement responsible people and therefore the background of the respondents was strong to answer this question. Only 3.03% participants responded, "do not know or not relevant". Large majority (63,64%) answered that the focus is at MDR requirements, and that sustainability risk management is primarily focused on patient safety and data security related risks. More than a quarter of the respondents (27,27%) answered that in addition to patient safety and data security risks, also some other sustainability risks are identified and managed systematically, and that growth potential exists. 6,06% of respondents were confident that sustainability risks are well under control and that sustainability risks are identified, managed, and reported systematically throughout the company. (Figure 25)

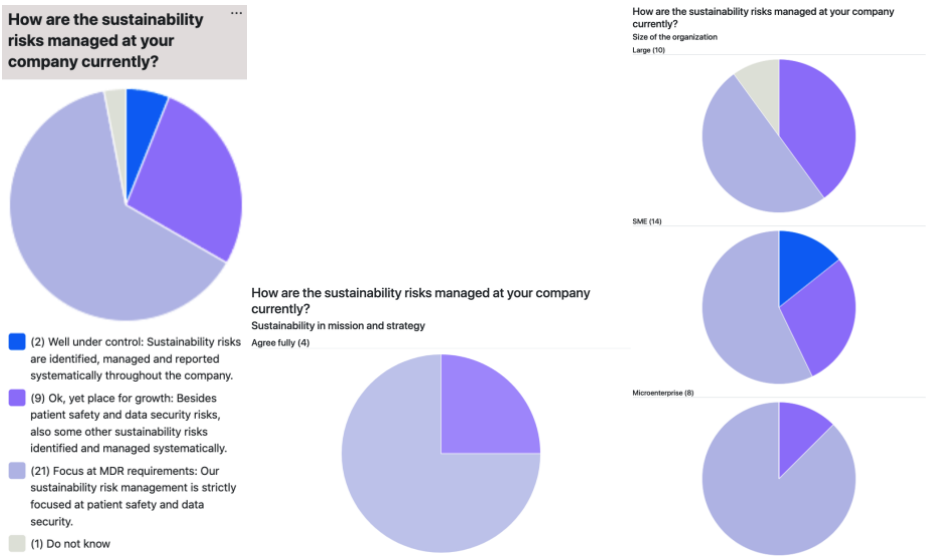

Figure 25: Medical device industry representative's views on how the sustainability risks are managed currently at their companies. Detailed view of the results at companies with sustainability mission and strategy. Detailed view of the results based on the company size.

It is interesting to see, that at the companies that have included sustainability in their mission and strategy, the status of sustainability risk management is not significantly different from the average. None of the companies consider that their sustainability risk management would be "well under control" level, but also at these companies, the focus is at patient safety and data security. The outcome is understandable as medical device manufacturers are strictly guided by industry specific regulations and ISO 14971 [122]. From that background it is on the other hand interesting to see how a third (33,33%) of the medical device manufacturers currently extend their risk management efforts beyond the immediate industry specific regulatory and standard based requirements and that it takes place not only at large medical device manufacturers that currently have sustainability reporting regulatory requirements [42] but also at smaller medical device manufacturers.

When the participants were asked to comment on the total results of all participants, they also highlighted that current sustainability risk management efforts have industry specific compliancy-based focus. Many respondents were satisfied with the overall view and gave credit to that to the legislation and high general ethics in the country. Some respondents commented on the limited

resources of small companies. One respondent pointed out that the significance of sustainability risks efforts may increase. Others challenged the industry to look beyond the most obvious, by inviting manufacturers of software based and software intense devices to 1) reconsider choice of used programming languages [123] and 2) set sustainability related requirements on platform hosting companies. Table 3 summarises views of medical device industry representatives on the status of sustainability related risk management.

Table 3: Views of medical device industry representatives on the status of the sustainability related risk management in the medical device industry

STATUS OF SUSTAINABILITY RELATED RISK MANAGEMENT	**RELATED QUOTES**
Current compliance focus	*"Patient and user safety is priority". "Compliance is in focus", "Many MD companies are small. It is natural that right now focus is on MDR. Bigger companies have more resources and possibility have several focus areas."*
Satisfaction due to current legislation and culture	*"Looks very good", "Good in large companies", "As a SaMD manufacturer, this part is well taken care of." "It is partly integrated in the company practices due to compliance efforts for MDR and legislation.", "Finnish companies are ethical in general.", "In larger perspective I see that the legislative background and requirements are well established in Finland, thus following the regulation is actually globally quite good achievement. Naturally outsourcing to other countries can be seen as a risk."*
Acknowledgment that significance of sustainability may increase	*"Sustainability risks are maybe not that often in focus, maybe this area is growing?"*
Challenge to think beyond the most evident, challenges also software companies	*"Sustainability is probably concentrating on using concrete resources wisely (water, raw materials, waste generation) but do we think about efficiency also with software and other immaterial production, such as focusing on computationally efficient programs that consume less energy and have indirect effects on the use of resources/ pollution etc. How would you consider the return of invest to switch back to C as it is the most energy efficient programming language? There is Rust quite close but then the rest are quite energy hungry."*
Identification of the large impact of hosting platform services	*"Requiring service providers (server providers) to be efficient in sustainability / environmental matters."*

Summary: Whereas the majority (63,64%) of medical device manufacturers are focused on the current regulative requirements and patient safety and data security, roughly a quarter of the industry is already a step ahead with sustainability risks management. 6,06% systematically manage and report sustainability risks throughout the company. Based on this sample, the companies spearheading sustainability risk management are SME sized well established medical device manufacturers that have customers both in EU and outside of EU.

4.4.2 Identification of Sustainability Risks

Evaluated statement*: "Company has identified sustainability risks."*

This statement investigates the sustainability risk identification. The results are divided. A third of the respondents (33,33%) agree partially with the given statement. Only 3,33% percent of respondents fully agree. On the other side, 36,67% disagree either fully (3%) or partially (26.67%). Relatively large percentage of participants (26,67%) respond that they do not know, or they consider the statement not relevant for them. Such respondents include quality and regulatory assurance professionals at large, SME sized companies as well as microenterprises. (Figure 26)

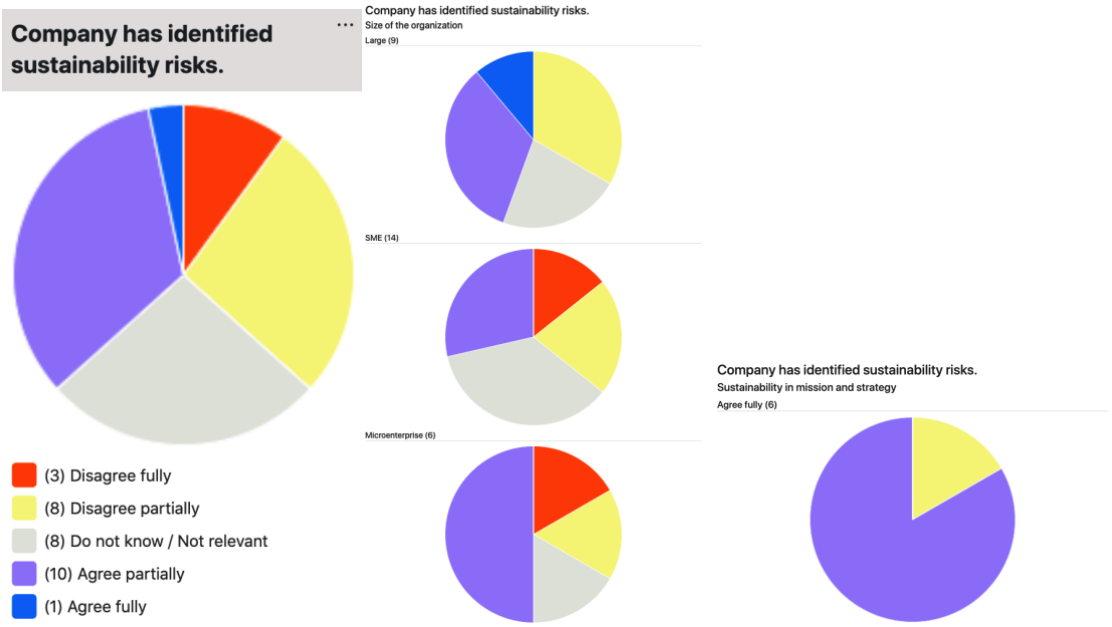

Figure 26: Medical device industry representative's views on whether their company has identified sustainability risks. Detailed view of the results based on the company size. Detailed view of the results at companies with sustainability mission and strategy.

Analysing the results from the company size perspective shows that the large companies are leading in sustainability risk identification. At SMEs roughly a quarter of respondents (28,57%) partially agree which interlinks to the earlier results revealing the high focus of the industry on the MDR requirements.

The responses of the companies which have sustainability as part of mission and strategy display a realistic, modest, yet ambitious attitude; despite the sustainability risk identification efforts, the respondents indicate improvement potential in this area. Nobody in this group answered "do not know" thus awareness is higher than in the industry on average.

The earlier question revealed that about two thirds conduct risk identification based on MDR, focusing on patient safety and data security related risks. This means that the identified sustainability risks of the two thirds of all respondents are patient safety and data security related risks. For example, current risk management includes identification of risks related to usage of hazardous materials, but with a strong patient, user, and employee protection focus.

Whereas EU current sustainability related reporting requirements including risk identification primarily impact large companies [42], it is to be expected that also small companies will be impacted either directly or indirectly within mid-to-long term time perspective [43] [114]. In addition to identification of sustainability risks, proposed legislation calls for identification of opportunities and impact [43].

Strong risk aware culture, and proactive identification of hazards, possible sequence of events, hazardous situations, and harm or damage across all organization [122] forms a firm basis identification of wider scope of sustainability risks.

Summary: The respondents' answers indicate that the medical device manufacturers in Finland have not currently identified sustainability risks to the extent possible. The results show a clear division in the responses. A third of the respondents (33,33%) agree partially that the company has identified sustainability risks. Only 3,33% percent of respondents fully agree. 36,67% of respondents disagree either fully (3%) or partially (26.67%). A relatively large percentage (26,67%) of respondents are unaware whether their company identifies sustainability risks, or they do not consider the matter to be relevant.

4.4.3 Mitigation and Management of Sustainability Risks

Evaluated statement: *"The company systematically mitigates and manages sustainability risks."*

When evaluating the sustainability risk mitigation and management related statement, 23,33% of the respondents agree either fully (6,67%) or partially (16,67%) with the given statement. At the same time, 40% disagree either fully (20,00%) or partially (20,00%) and 36,67% do not know or do not find the statement to be relevant. (Figure 27)

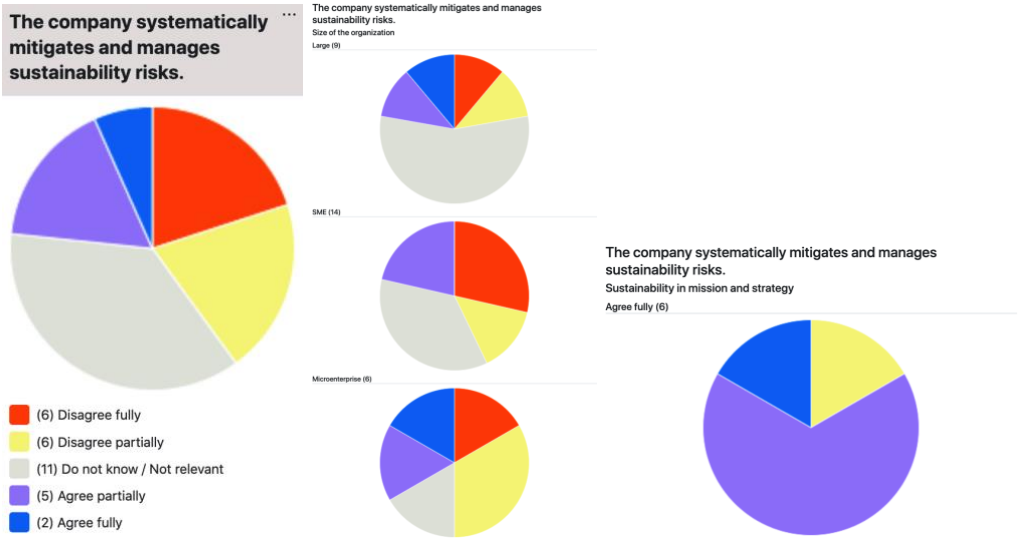

Figure 27: Medical device industry representative's views on whether their company systematically mitigates and manages sustainability risks. Detailed view of the results based on the company size. Detailed view of the results at companies with sustainability mission and strategy.

The results relating to this statement are aligned with the results relating to the risk identification. Only identified risks can be mitigated and managed. The fine differences suggest that respondents view that not all identified risks are systematically mitigated and managed.

In small companies it is easier to know what is done or not done. This can be seen also in the results; the unawareness ("do not know or not relevant" answers) is highest at large companies. This indicates that ESG related risk mitigation and management is not in practise closely linked to the work of quality and regulatory assurance professionals.

The companies that have sustainability as part of mission and strategy have the highest level of awareness, but also their answers are dominated by "partially agree" and "partially disagree" answers, which indicates that representatives of these companies consider that the sustainability risks are not yet systematically mitigated and managed to the extend they could be.

Summary: About a quarter of all respondents, (23,33%) of the respondents agree either fully (6,67%) or partially (16,67%) with the given statement claiming

that their company systematically mitigates and manages sustainability risks. At the same time, 40% disagree either fully (20,00%) or partially (20,00%) and 36,67% do not know or find the topic relevant.

4.4.4 Organization's Involvement in Sustainability Risk Management

Evaluated statement: "Whole organization participates in identification of sustainability risks" and "Whole organization participates in mitigation of sustainability risks."

The results relating to these two statements are almost identical and as they are related, they are introduced and analysed together. The results display quite a strong message: 63,33% disagree fully (33,33%) or partially (30%) for identification and 56,67% relating to mitigation and management (33,33% disagree fully, 23,33% disagree partially). In other words, this means that at these organizations the whole organization is not involved in identification, mitigation, and management of sustainability risks.

Only 16,67% agree partially that the whole organization participates in the identification of sustainability risks. About a quarter of respondents (26,67%) agree fully (3,33%) or partially (23,33%) that the whole company participates in sustainability risk mitigation and management. About 20% of respondents do not know or find it relevant whether the whole organization participates in the identification, mitigation, and management of sustainability risks. Based on the results, involvement of personnel is higher the smaller the company. (Figure 28)

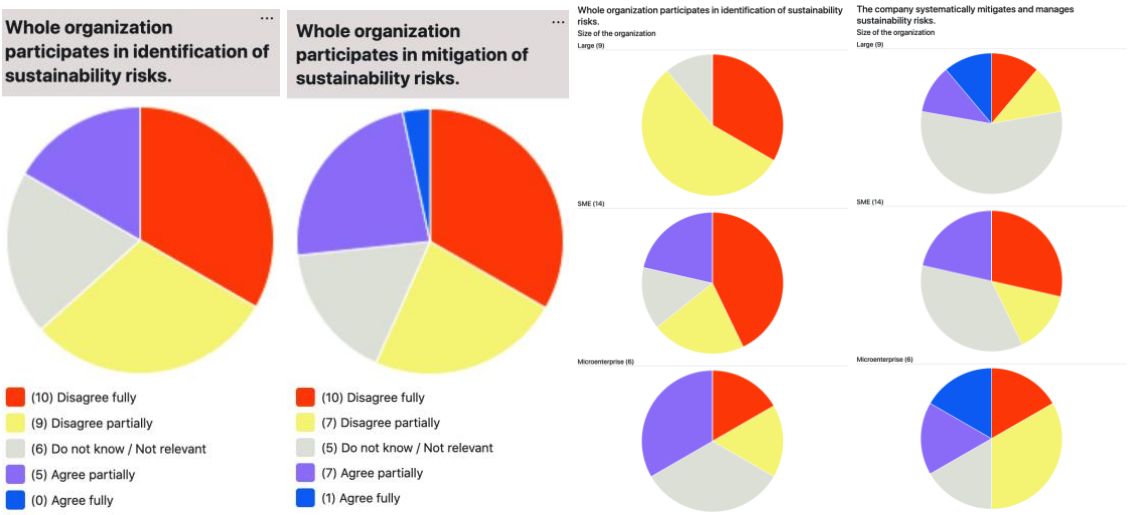

Figure 28: Medical device industry representative's views on whether at their company the whole organization participates in identification and mitigation of sustainability risks. Detailed view of the results based on the company size.

At medical device manufacturers, patient safety related risks are identified, mitigated, and managed throughout all processes and the product lifecycle. In its 175 pages MDR mentions 'risk' 243 times [10]. For a good reason, patient safety is deeply embedded also in medical device manufacturers' set of values. Respectively, it can be assumed that if sustainability is not part of shared values, and sustainability risk identification, mitigation and management activities are not embedded to processes and product lifecycle, the impact of related activities is limited.

Summary: At the majority of the medical device manufacturers participating in the survey, the whole organization is not involved in the identification, mitigation, and management of sustainability risks.

4.4.5 Significance of Environmental Risks vs. Social and Governance

Evaluated statement: *"The most significant sustainability risks of the company are relating to Environment (vs. Social or Governance)."*

Only a small minority of respondents had strong opinion about this matter. 6,67% fully agreed that the significant sustainability risks of the company are relating to environment (versus social or governance). This could be interpreted so, that

according to these respondents, the other sustainability risks are currently managed better, making the environment related risks most significant sustainability risks for their company. At the same time 10% of respondents fully disagreed with the given statement. Most respondents (56,67%) either partially agreed (26,67%) or disagreed 30,00%. About a quarter of the respondents (26,67%) did not know or find it relevant. (Figure 29)

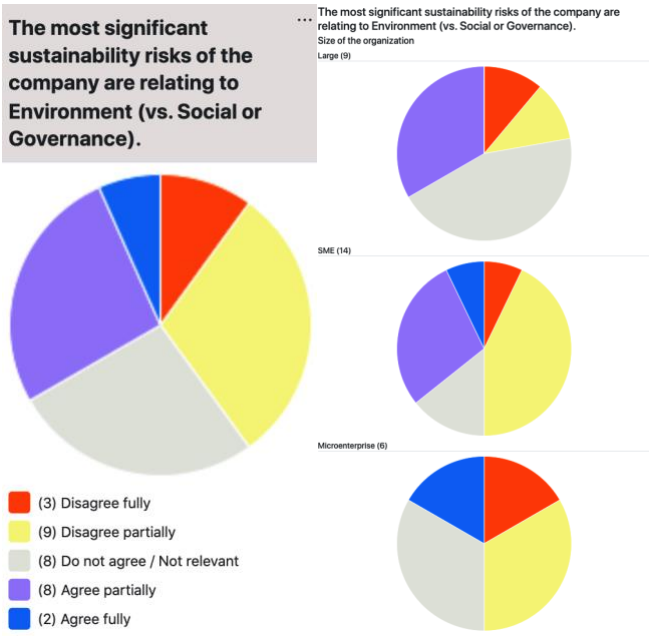

Figure 29: Medical device industry representative's views on whether at their company the most significant sustainability risks are relating to environment (vs. social or governance) factors. Detailed view of the results based on the company size.

Partial agreements indicate increased environmental awareness among the medical device manufacturers based in Finland, whereas partial disagreement refer to the core business of the medical device manufacturers where patients' health related risks have highest significance. [10] This latter view seems to be particularly dominant at the small and medium sized as well at microenterprises. "Do not know or not relevant" option was the most common at large medical device manufacturers.

Ambiguity of the answers reflects the reality where on the one hand there is need for increased environmental awareness [7], yet on the other hand the

management of social related risks and robust governance remain at the core of medical device manufacturers' operations.

Summary: Only 6,67% of representatives of medical device manufacturers based in Finland participating in the survey, fully agreed that the most significant sustainability risks of the company are relating to environment (vs. social or governance). This indicates the inherent strong social and governance focus of medical device industry.

4.4.6 Sustainability Risks as Source of Product and Process Innovation

Evaluated statement: *"Identified sustainability risks are used as source for product innovation." and: "Identified sustainability risks are used as source for process innovation."*

As the results of the two statements are so similar, the observations are grouped together. Given the statements whether identified sustainability risks are used as source for product or process innovation, no respondent fully agreed. A third of respondents (33,33%) partially agreed that sustainability risks are used for product innovation and 40% that for process innovation. Roughly another third of the medical device industry representatives participating the workshop did not know or find either of the statements relevant. At the same time, 6,67% of respondents fully disagreed with both statements. Remaining respondents disagreed partially on the claim stating that identified sustainability risks are used as source for product (23,33%) or process innovation (20%). (Figure 30)

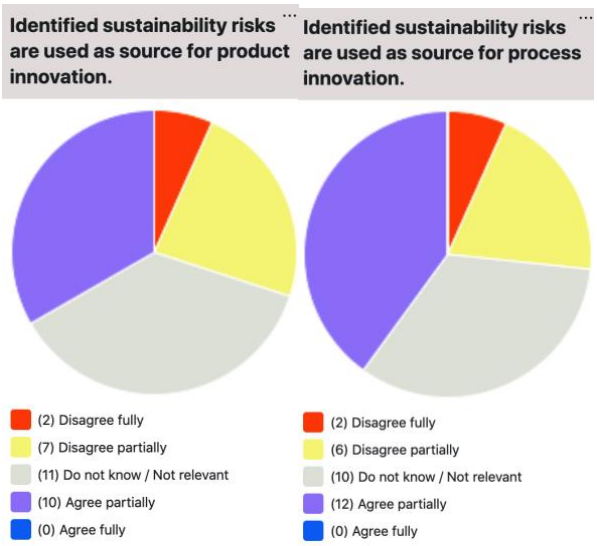

Figure 30: Medical device industry representative's views on whether at their company identified sustainability risks are used as source for product or process innovation.

An attempt to interpret the results is based on the earlier outcome that two thirds of respondents shared that their sustainability risk management efforts are focused on patient safety and data security risk management. The quality management systems implemented according to ISO 13485 have in-built mechanisms and processes according to which root cause analysis of risks and deviations will contribute to both medical device and / or process improvements. This can explain partial agreements. The respondents are potentially critical whether the improvements can be considered as innovations of bigger scale vs. improvements of smaller scale. The lack of full agreements may also reflect the fact that identification of wider range of sustainability risks is not yet happening and therefore only partial agreement is possible. Full disagreements are strong statements. Partial disagreements imply that respondents do not fully disagree, but view that sustainability risks have offered random input to product and process innovations. According to the respondents, it is still far from a status where one could say the sustainability risks would act as source for product and process innovation.

Among the large medical device manufacturers, the level of partial agreement is the highest. It is slightly surprising that at microenterprises the percentage of “do not know or not relevant” is the highest. This may be due to microenterprises’ innovation efforts being typically focused on the original value proposition. (Figure 31)

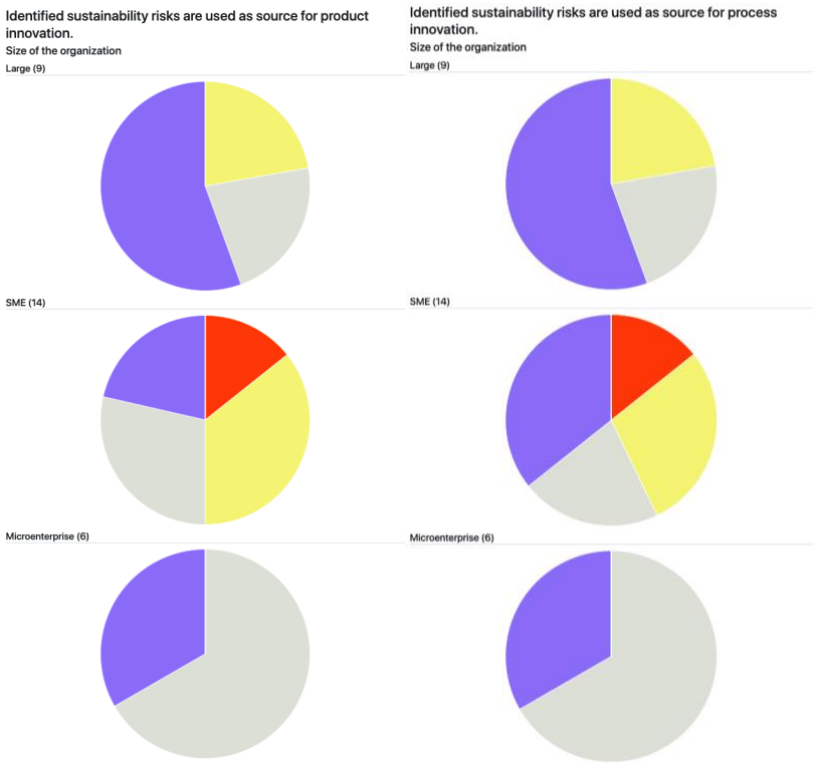

Figure 31: Medical device industry representative’s views on whether at their company identified sustainability risks are used as source for product or process innovation based on company size.

One of the key findings of FIBS 2021 research on status of sustainability among largest Finnish companies was that despite established sustainability efforts, very few companies use sustainability as source of product and process innovation or create sustainability originated disruptive products or ways of working [19].

Summary: Sustainability related risks are not a widely used source of product and process innovations among medical device manufacturers based in Finland. About two thirds of medical device industry representatives disagree or are not aware if sustainability risks are used as a source for product or process

innovation. The remaining third agrees partially, but not fully that sustainability risks act as a source for product and process innovation.

4.4.7 Views on Potential Implications of Sustainability Risk Reporting Requirements

Workshop participants provided views on what anticipated increased EU's sustainability risk reporting requirements could potentially bring along. Insights were provided on 1) potential new expectations, 2) new opportunities and 3) actions needed.

4.4.7.1 New Expectations

Workshop participants expect that EU’s proposed sustainability risk reporting requirements to impact customer expectations which in turn will impact their processes and product development. Concerns were raised that increased reporting, and potential related certifications, may turn out to be a new market entry barrier for small companies. Table 4 summarizes the anticipated new requirements and related quotes from the representatives of medical device manufacturers located in Finland.

Table 4: Anticipated requirements relating to potential implications of future EU's sustainability risk reporting requirements

NEW ANTICIPATED REQUIREMENTS	RELATED QUOTES
Customer requirements	*"Sustainability risks / sustainability certification", "Customer requirements will increase for sustainability risks"*
Development of new devices with sustainability in mind	*"Energy savings through computationally efficient / lower cost of programming"*
QMS changes	*"New process to the quality system, if not there already", "Environmental requirements as part of the process / QMS", "New processes for manufacturing waste, recycling etc.", "Define recycling of medical device and package materials in IFU".*
Verification and communication of ESG data	*"Increased documentation and reporting e.g., energy management, waste management, IFU changes impacting consumers (recycling of device and packaging)", "Very little impact on business, more paperwork", "More paperwork"*
Changes to risk management	*"Documented risk assessment for sustainability risks", "Sustainability risk to be included in product risk management", "Documented plan for decreasing sustainability risks"*
New standards and / or certifications	*"Public tenders will require sustainability certification or statement", "Same elements than environment management system standard regarding to environment aspects etc."*
New market barrier for small companies	*"New market barrier for small companies. Could be later seen as opportunity once the recycling / waste management is handled"*

4.4.7.2 New Opportunities

Representatives of medical device industry in Finland foresee that introduction of new EU level sustainability risk related reporting demands would also lead into opportunities relating to improved, differentiated products and processes. Identified opportunities included also improved employee motivation, marketing, and financial value. (Table 5)

Table 5: Anticipated opportunities relating to potential implications of future EU's sustainability risk reporting requirements

NEW ANTICIPATED OPPORTUNITIES	RELATED QUOTES
Improved products	*"More efficient products", "Improvement of products"*
New materials	*"Usage of new materials (non-virgin)", "More use of material that can be recycled, packaging", "Better availability with products built with innovative sustainable readily available materials?"*
Differentiation	*"Potential to differentiate from competitors, as we do have more sustainable solutions for some real-world problems than competitors."*
Improved processes	*"Improvement of manufacturing processes", "Innovation in design and development projects"*
Employee experience	*"Motivates the personnel"*
Marketing value	*"Better company image", "new opportunities for company image", "Good publicity", "Could we differentiate in marketing?", "Tool to communicate externally about companies approach to sustainability"*
Financial benefits	*"Improved economy", "Potential business opportunities", "Business opportunities arise for the companies who are able to adopt this in a convincing manner."*

4.4.7.3 Identified Actions Relating to Evolving Legislative Landscape

The representatives of medical devices identified areas of actions relating to potential implications of future EU's sustainability risk reporting requirements. The actions include mapping areas of most significant impact, planning for various scenarios, increasing awareness and competence, adjustment of processes and policies, adjustments to risk management as well as communication and stakeholder engagement. (Table 6). In this context, a microenterprise also expressed a valid concern relating to heavy burden which additional formal reporting requirements would set particularly to a company of that size.

Table 6: Identified actions needed relating to potential implications of future EU's sustainability risk reporting requirements

IDENTIFIED ACTIONS	**RELATED QUOTES**
Mapping and planning	*"Identifying the biggest environmental impacts and social / ethical impacts of your company. Then considering how to improve.", "Thinking outside the box and looking forward to the future when it comes to sustainability. Are any other sustainability factors than obvious energy consumption and water consumption, disposal of thrash? What if your product becomes really big and everyone has it, what does it mean?"*
Awareness programs and guidance	*"More awareness", "Awareness programs and mapping of biggest opportunities of impact", "Maybe training or awareness is needed around this" "Guidance for recycling and waste collection regarding MD"*
Process and policy adjustments	*"We can think more about reducing waste"*
Risk management adjustments	*"EU in general seems to be taking quite ambitious goals, so risk management to be able to be complaint in the future would definitely be needed."*
Communication and stakeholder engagement	*"Stakeholder pressure", "Regular communication on the plans and goals towards the staff and key stakeholders", "Companies should provide sustainability reports (annual, bi-annual?), "Please NO more formal reporting liabilities for a micro company"*

4.5 SUSTAINABILITY RELATED RESOURCES

This section provides insights about the available resources such as knowledge, financial resources, and personnel motivation that the medical device manufacturers may require to materialize increased sustainability impact.

4.5.1 Personnel with Sustainability Competence

Evaluated statement: *"We have personnel who have sustainability competence."*

One third (33,33%) of organizations in the medical device industry in Finland have personnel who have sustainability competence (23,33% agree fully, 10% agree partially). At the same time, about a quarter of the respondents (26,67%) viewed that their personnel do not have sustainability competence (6,67% fully disagree with the given statement and 20% partially disagree). 40% of the respondents chose the alternative "do not know or not relevant" implying that such competence is not visible within the organization. (Figure 32)

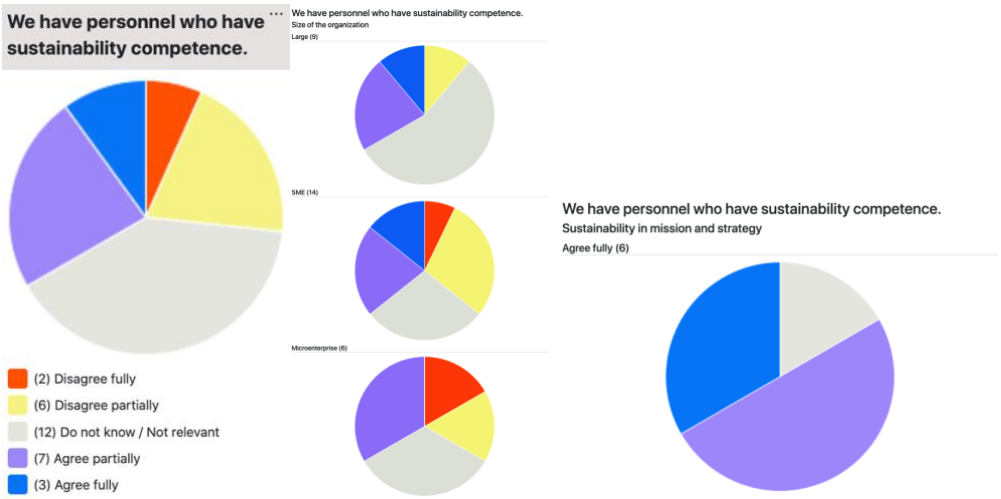

Figure 32: Medical device industry representative's views on whether their company has personnel who have sustainability competence. Detailed view of the results based on the company size. Detailed view of the results at companies with sustainability mission and strategy.

Based on the low portion of "fully agree" and "fully disagree" answers, part of the perceived competence is strictly relating to compliance with the current regulative

requirements for medical device manufacturers that sets a basis for sustainability competence in this industry.

High level of unawareness (“do not know or not relevant” answers) may indicate that sustainability competence is not as familiar to the respondents as e.g., quality related competence. It may also reflect the level of activities and communication relating to sustainability within the organisations. Earlier results revealed that at majority (62,07%) of the researched organizations, the quality management system does not include references to sustainability or sustainability factors. Certain QMS processes require the involved personnel to have certain competences. If sustainability factors were integrated to processes, they would be expected to come across positively in internal and external communication. This in turn would impact the general level of competence awareness. In large companies the unawareness level of the respondents is even higher than in the rest of the industry. Personnel working for companies that have sustainability in their mission and strategy have higher level of sustainability competence than the industry on average.

To solve the sustainability related challenges, also medical device industry will need personnel with sustainability competence. As sustainability is an overarching concept, practical implementation of it, requires not only specialists but competence throughout the organization as each decision can potentially have positive or negative sustainability impacts. In addition to building competencies, development of values and culture that authentically embrace sustainability need deliberate efforts [124].

Summary: Only about a third of the organizations perceive that their organizations have personnel who have sustainability competence.

4.5.2 Dedicated ESG (Environment, Social and Governance) Professionals

Evaluated statement: *“Our company has dedicated ESG (Environment, Social and Governance) professionals.”*

A closer look at the current level of competences reveals that more than half (58,62%) of the medical device industry companies do not have professionals dedicated to work with environmental, social and governance issues (48,28% disagree fully, 10,34% disagree partially). More than quarter of the respondents (27,59%) do not know whether the organization has such professionals. In case of large companies, more than half (55,56%) of the respondents belong to that group. (Figure 33)

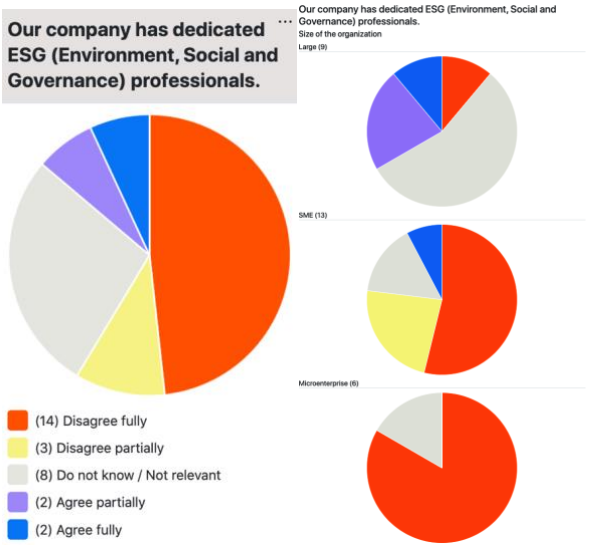

Figure 33: Medical device industry representative's views on whether their company has dedicated ESG (Environment, Social and Governance) professionals. Detailed view of the results based on the company size.

With one SME exception, large companies of this sample, are the ones having dedicated EGS resources. Interestingly, about half of the participants of this research that work in quality and regulatory assurance roles at large companies, do not know, or think it is relevant to them whether their organization has ESG professionals. This implies that at the large medical device manufacturers the quality and regulatory assurance professionals (role that the most respondents have), would not work closely with the ESG department.

Multiple viewpoints exist, whether having a separate unit with ESG competence serves a company best or not, and therefore each company needs to identify best approach for themselves. Ideally ESG professionals bring in latest knowledge

and competence, train, coach and coordinate the whole organization to implement continuous impactful sustainability related initiatives of different scale and scope. In the worst case, the role of the ESG professionals remains marginal and reporting focused, and management and operative organization outsource to them responsibility that they themselves should take ownership of.

Comparing the result with the previous statement regarding sustainability competence of the personnel reveals that the participants of the workshop consider that that some sustainability competence exists within the organizations despite the potential lack of dedicated ESG professionals.

Summary: Whereas ESG professionals work at large medical devices manufacturers, it is not a common role at most of the medical device manufacturers based in Finland.

4.5.3 Sustainability Competence of Management and Board

Evaluated statement: *"The company management and board have sustainability competence."*

Only 3,33% of the respondents fully agreed that the management and board have sustainability competence and 23,33% partially agreed, indicating potential for improvement in this area. At the same time, 20% of the respondents partially disagreed with the given statement. Surprisingly large percentage of respondents (53,33%) answered "do not know or not relevant". (Figure 34)

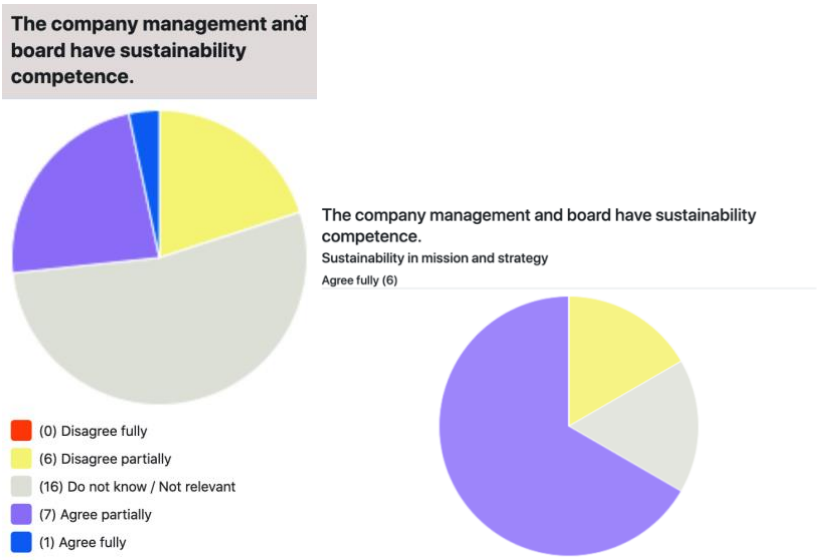

Figure 34: Medical device industry representative's views on whether their company's management and board have sustainability competence. Detailed view of the results at companies with sustainability mission and strategy.

The respondents do not demonstrate strong confidence in their company's management and board's sustainability competence. The results also indicate that even if the management and board would have such competences, they have not been able to demonstrate and communicate it to their organization.

The results are interesting considering that as indicated earlier, in more than half of the organisations the top management to some extend talks about sustainability and have included it the mission and strategy of the company. Closer analysis reveals a strong link between the organizations with sustainability competence in personnel and the organizations whose management and board have sustainability competence.

The confidence in management and board competence is higher at companies that have sustainability in mission and strategy. However, none of the respondents in that group answered "agree fully" which demonstrates the high expectations set for the management and the board.

The role of the board and management is important in relation to how sustainability is integrated to the mission, strategy, and operations. By aligning

the sustainability reporting with the financial reporting, the EU aims to increase board and management level commitment as top management becomes more directly accountable for sustainability reporting [43].

Summary: The results indicate lack of confidence and awareness relating to the sustainability competence level of the members of the management and boards in the medical device industry.

4.5.4 Respondents' Own Perceived Sustainability Competence

Evaluated statement: "*I have adequate sustainability competence.*"

40% of the respondents feel confident about their own sustainability competence (agree fully 6,67%, agree partially 33,33%). On the contrary, about a similar number of respondents (43,34%) feel that they do not have adequate sustainability competence (disagree fully 13,34%, disagree partially 30%). (Figure 35)

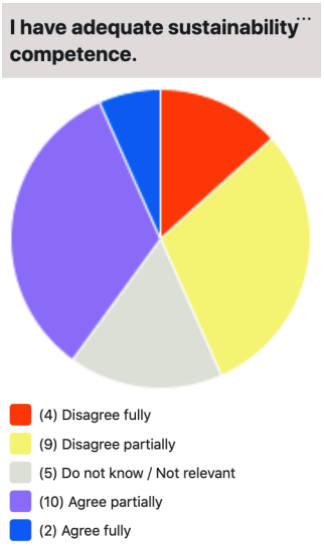

Figure 35: Medical device industry representative's views on whether they themselves have adequate sustainability competence.

The respondents who had a strong opinion about their competence (either fully agree or disagree with the given statement), were a minority (in total 20,01%). This result indicates that it is not straightforward to determine what could be

considered as adequate sustainability competence. Comparison with the results relating to sustainability competence of the personnel and that of the management and board, reveals that the respondents are most confident at their own sustainability competence. This information, coming from the quality and regulatory assurance professionals sends a strong signal to their organizations that quality and regulatory compliance personnel could potentially internally spearhead the transition towards more sustainable operations.

Siva et al. highlight quality management professionals' potential role in increasing sustainability competencies at their organisations, due to their vertical depth understanding and skills to implement horizontal coordination within the organization [125].

Summary: 40% of the respondents feel confident about their own sustainability competence. Majority of the respondents have a quality or regulatory assurance role at a medical device manufacturer.

4.5.5 Awareness of Proposed CSRD and following Implications

Evaluated statement: *"Proposed Corporate Sustainability Reporting Directive (CSRD) and its implications have been discussed at our company."*

Over half (56,67%) of the medical device manufacturers based in Finland do not know whether CSRD and its implications have been discussed at their company, or do not consider this to be relevant. 20% of the respondents are aware of such discussions, agreeing either fully (13,34) or partially (6,67%). About the same percentage of respondents (23,34%) know that such discussions do not take place, disagreeing fully (16,67%) or partially (6,67%) with the given statement. (Figure 36)

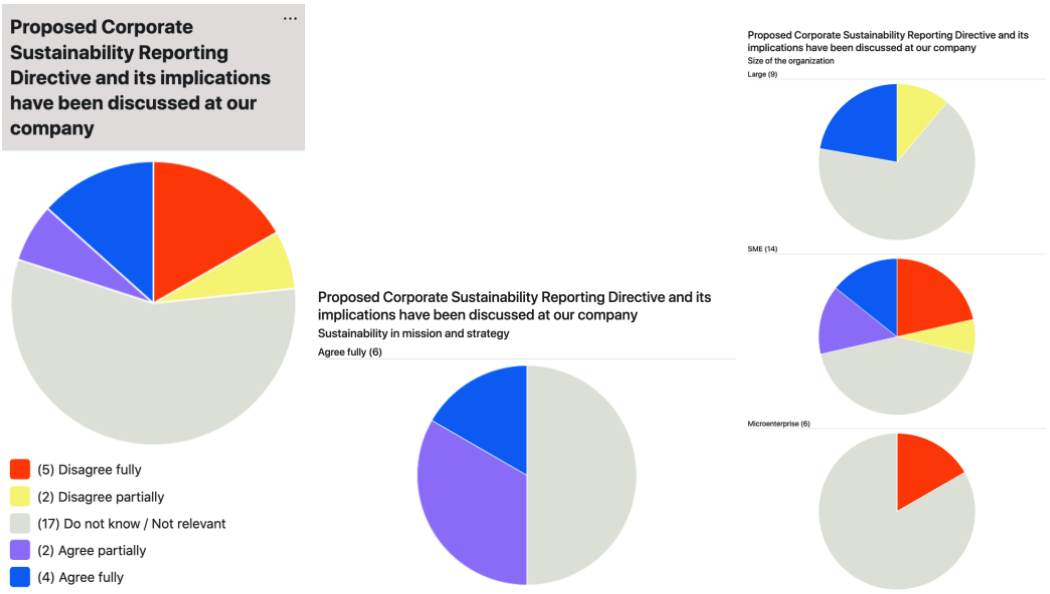

Figure 36: Medical device industry representative's views on whether European Commission's proposed Corporate Sustainability Reporting Directive and its implications have been discussed at their company. Detailed view of the results at companies with sustainability mission and strategy. Detailed view of the results based on the company size.

Higher level of awareness can be seen at companies that have sustainability in mission and strategy. CSRD related discussions are taking place at some of the large medical device manufacturers and SMEs.

Whereas MDR compliance is a market entry requirement for medical device manufacturers, the CSRD "merely" sets past, status and plan related reporting requirements to provide high quality, reliable, transparent, and comparable information for various stakeholders' decision-making. The aim is to assist directing financial resources to sustainable organizations with real impact. CSRD will primarily impact large, and stock listed companies operating in the EU, but it is expected to indirectly impact to also other organizations [43]. At the time of writing the report, European Financial Reporting Advisory Group (EFRAG) [126] continues to work on standards that specify in more practical detail the requirements of CSRD. As medical devices are a global industry, also related works of the U.S. Securities and Exchange Commission and International Sustainability Standards Board may be relevant for them.

Summary: Corporate Sustainability Reporting Directive (CSRD) proposed by the European Commission and its implications have been discussed in 20% of companies representing medical device industry based in Finland.

4.5.6 Importance of Tracking Development of Sustainability Regulation Initiatives

Evaluated statement: "*Following development of EU's regulative initiatives relating to sustainability is considered strategic in our company."*

Over half of the respondents (53,33%) do not know or do not think it is relevant if following the development of EU's regulative initiatives relating to sustainability is considered strategic at their company. Only 20% agree fully (6,67%) or partially (13,33%) with the given statement. The percentage who disagrees fully (13,33%) or partially (13,33%) is about in similar level in total (26,67%). (Figure 37)

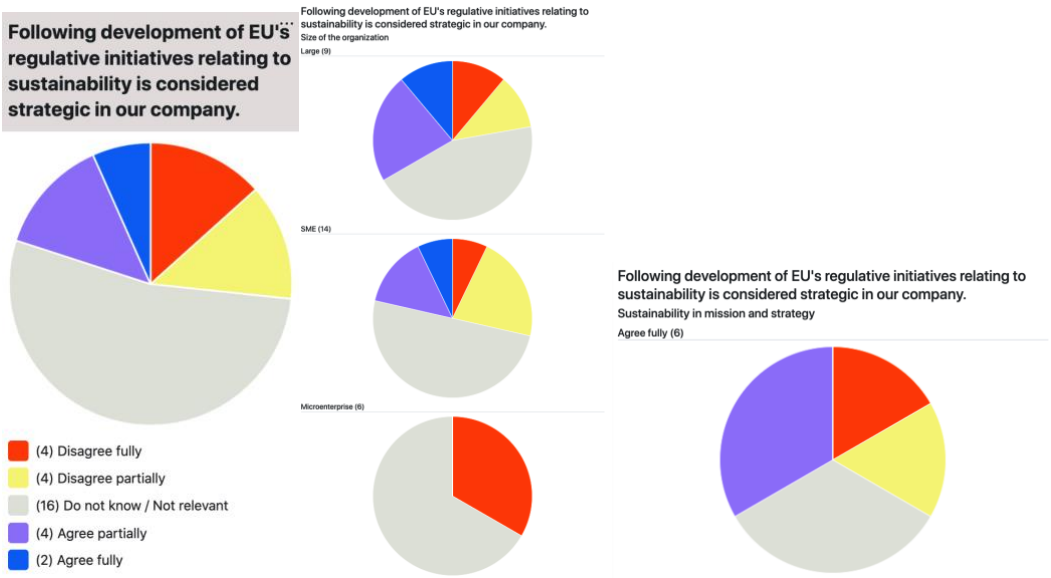

Figure 37: Medical device industry representative's views on whether following development of EU's regulative initiatives relating to sustainability is considered strategic at their company. Detailed view of the results based on the company size. Detailed view of the results at companies with sustainability mission and strategy.

Considering that respondents have quality and / or regulatory assurance roles at their companies, this outcome reveals that in practise the regulatory compliance efforts are primarily focused on medical device specific regulatory requirements

and related standards, which together form a large and constantly evolving regulatory landscape to comply with. Even though contents of MDR became public in 2017, medical device industry is still getting adjusted to the requirements [127]. In April 2022, a year after MDR becoming effective, 85% of medical devices in the market still had not been issued MDR certificates. Underlying reasons include the actual requirements, availability of Notified Bodies, and the longer time-to-certification with Notified Bodies [128, p. 6]. Similarly, there have been and are many other emerging regulations and guidelines e.g., related to data security and AI, both becoming increasingly dominant among medical devices, as well as practises such as the European Database on Medical Devices (EUDAMED), that increasingly will impact the work of employees responsible for quality and regulatory compliance. Already now the operational responsibility of regulatory requirements compliance can be handled in different departments, for example employment related regulations are typically handled outside the regulatory assurance team.

Analysis reveals that most companies that follow sustainability related regulatory initiatives have also discussed CSRD. Similarly, many companies that have not put strategic focus at getting familiar with the regulative initiatives, have not discussed potential CSRD implications either. The number of companies that disagree (In total: 26,67%, fully 13,33% and partially 13,33%) is connected to the earlier results that similar percentage of respondents disagreed having sustainability as part of mission and strategy (In total: 32,20%, fully 3,33% and partially 28,87%)

Even though the EU’s regulatory initiatives relating to sustainability are expected to have direct impact first at large companies, the general awareness is not much higher at large companies. This tells either about the lack of internal communication and / or that the current regulatory requirements already set a workload on the employees that limits the bandwidth to the immediate requirements. Among the companies that fully agree that sustainability is in their mission and strategy, none fully agree that following the related regulatory

initiatives would be strategic for their company, which is surprising and leaves room for development.

Summary: Over half of the respondents (53,33%) do not know or do not think it is relevant for them to know if following the development of EU's regulative initiatives relating to sustainability is considered strategic at their company. Based on the sample, the 20% of medical device manufacturers based in Finland currently consider it to be strategic (fully agree 6,67%, partially agree 13,33%).

4.5.7 Financial Resources to Improve Sustainability of the Operations

Evaluated statement: "*Our company has financial resources to invest in order to improve sustainability of the operations.*"

The results relating to availability of financial resources to improve sustainability of operations are divided as almost 20% (20,69%) agree, either fully (6,90%) or partially (13,79%) and at the same time almost 40% (37,93'%) disagree, either fully (13,79%) or partially (24,14%) with the evaluated statement. The rest, 41,38% of respondents, fall into two different groups: some respondents do not know if the company possesses financial resources to invest in sustainability improvements or whereas the others do not consider this topic to be relevant for their company. The unawareness can imply low confidence in the company's financial situation and / or of low level of communication relating to the company's financial stability and / or priorities. (Figure 38)

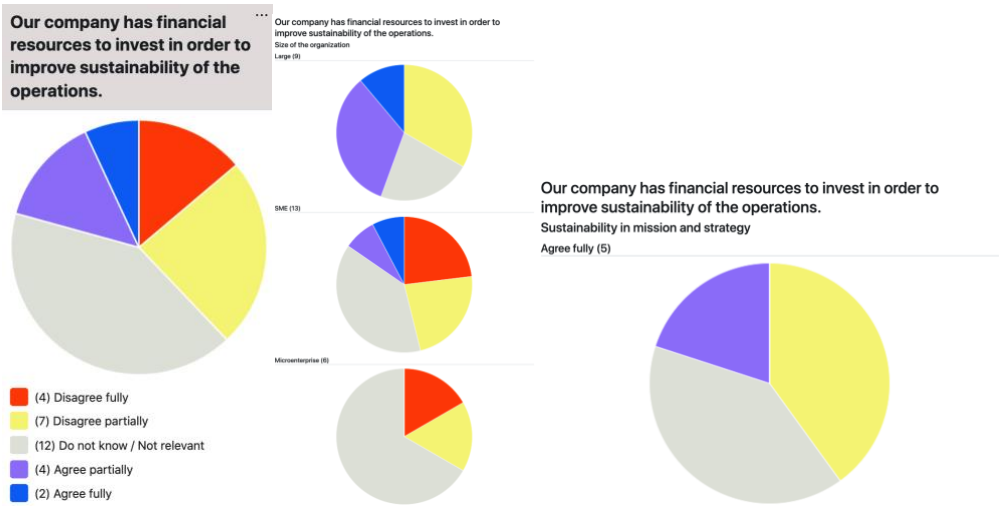

Figure 38: Medical device industry representative's views on whether their company has financial resources to invest at improving sustainability of the operations. Detailed view of the results based on the company size. Detailed view of the results at companies with sustainability mission and strategy.

Respondents at large manufacturers are clearly more confident about the financial resources of their employers to improve sustainability of the operations than their peers at SMEs and microenterprises. While 44,44% of respondents at large companies agree fully (11,11%) or partially (33,33%), it is not straightforward, as the scale of operations and needed investments are more significant and multiple competing priorities exist. 33,33% of the respondents at large manufacturers partially disagree that there would be financial resources to improve sustainability, the rest do not know or find it relevant to consider that question. Analysis of companies that fully agree that sustainability is in their mission and strategy, reflects low confidence in the available resources. These companies potentially have a higher level of understanding than on average of the practical implementation demands.

In addition to competences, financial resources are required. Compared to the earlier identified ambitions of making ESG improvements, the level of financial resource availability sends an alarming signal relating to the feasibility of addressing those aspirations. A positive development to address the concern is the development of EU's financial markets where the regulations aim to direct

financial resources towards companies that operate in a sustainable manner [43] [104].

Summary: Only about 20% of representatives of medical device manufacturers based in Finland are confident with their company's financial resources to invest into improving sustainability of their operations. Proportionally, the highest level of confidence and awareness of financial capabilities is found at large medical device manufacturers.

4.5.8 Confidence in Transformation towards More Sustainable Operations

Evaluated statement: *"I am confident that our company will make transformation towards more sustainable operations during the next 3 years."*

More than 70% (72,41%) of the respondents agree either partially (55,17%) or fully (17,24%) that their company will make transformation towards more sustainable operations during the next 3 years. 17,24% do not know or find it relevant, 10,34% disagree partially, nobody disagrees fully. (Figure 39)

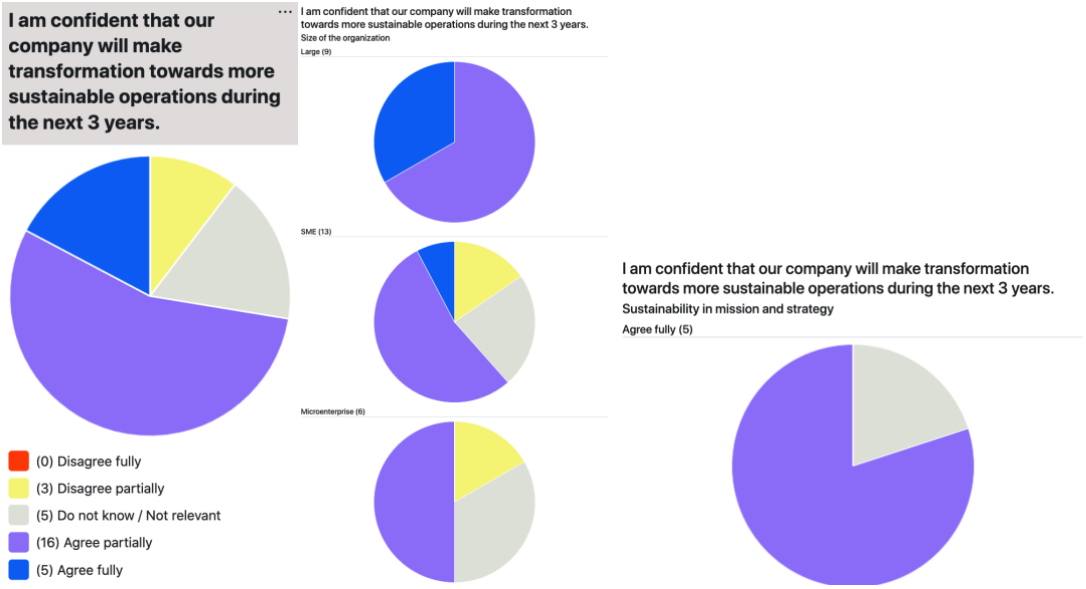

Figure 39: Medical device industry representative's views on whether they are confident that their company will make a transformation towards more sustainable operations during the next 3 years. Detailed view of the results based on the company size. Detailed view of the results at companies with sustainability mission and strategy.

The results do not reveal directly, why the respondents agreeing partially, did not agree fully. Is it due to the current lack of sustainability competence in the organization or confidence in availability of finances as indicated earlier? Or the fact that sustainability beyond current regulative requirements is still not in the company's mission and strategy and / or due to low level of confidence in the sustainability competence of the management and board? Or is it due to the respondents being very pragmatic and critically minded in general? "Transformation towards more sustainable operations" may be perceived as a major initiative including potentially adjustments to multiple processes and products and therefore it might take more than 3 years. The industry is still dealing with impacts of MDR requirements even if there have been multiple years to adjust to those. MDR as such still was a logical follow-up for MDD following same logic to large extend. Sustainability as a theme challenges companies to review their operations from new perspectives.

Analysing the results from the company size perspective reveals that the confidence is highest at the large medical device manufacturers, where up to 100% of respondents agree to some extend with the given statement. Representatives at companies that have sustainability in their mission and strategy take a pragmatic approach; the majority partially agrees, and the rest do not want to speculate on the future. This reflects the respondents' high level of practical understanding of the changes required and of the daily realities.

Summary: More than 70% of the representatives of medical device industry based in Finland have some level of confidence that their company will make some level of transformation towards more sustainable operations during the next three years.

4.5.9 Need of Additional Competence or Assistance to Make Sustainability Transition

Evaluated statement: "*Our organization will need additional competence / assistance to make transition towards more sustainable operations during the next 3 years."*

About two thirds of the research participants (65,52%) view that their organization will need additional competence and / or assistance to make transition towards more sustainable operations during the next 3 years (agree fully 20,69%, agree partially 44,83 %). About 20% (20,69%) of the respondents, do not know or do not consider this relevant whereas 13,79% of respondents partially agree, and nobody fully disagrees. (Figure 40)

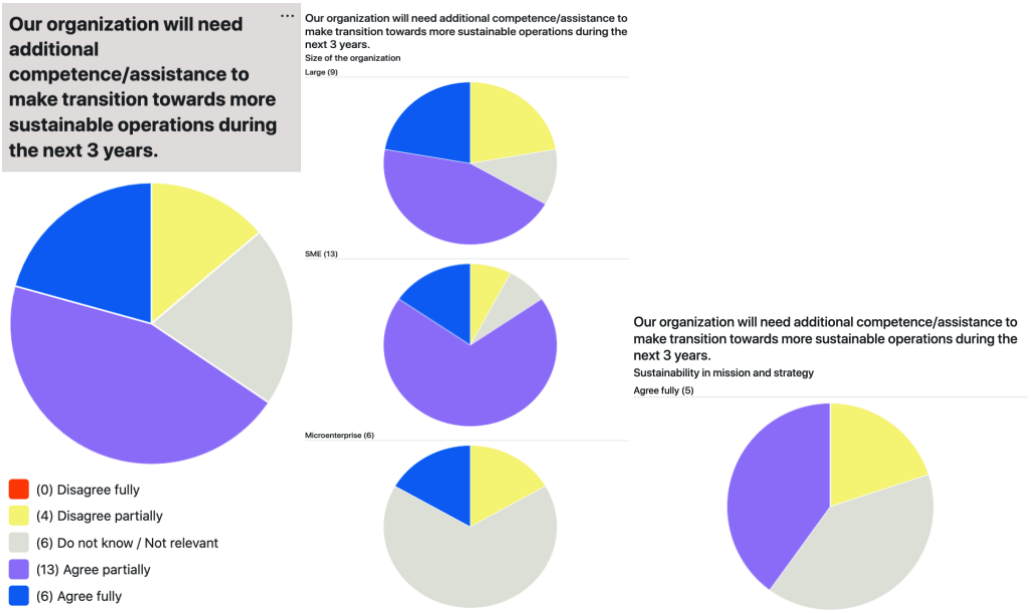

Figure 40: Medical device industry representative's views on whether their organization will need additional competence/assistance to make transition towards more sustainable operations during the next three years. Detailed view of the results based on the company size. Detailed view of the results at companies with sustainability mission and strategy.

At large manufactures the total results are almost symmetrical to those of the whole industry sample but at SMEs the recognition of the need of additional competence and assistance is even higher as up to 84,62% agree either fully (15.38%) or partially (69,23%.).

Medical device manufacturers that fully agreed that sustainability is part of their mission and strategy have the strongest confidence in the competence of their personnel and this answer aligns with that confidence as none of the respondents of this sub-group responded, "fully agree". Instead, the "partially agree" and "partially disagree" answers demonstrate existence of inhouse competence. "Do

not know" answers reflect acceptance of unknown future, and that future may bring something that is currently not clear.

The results outline how the quality and regulatory assurance professionals at medical device manufacturers based in Finland evaluate the sustainability related learning challenge. The results reflect the modest mentality of the industry that is used to face and deal with continuously changing new demanding requirements and circumstances and where continuous learning is a constant requirement regardless of the role.

Summary:

About two thirds of the research participants (65,52%) view that their organization will need additional competence and / or assistance to make a transition towards more sustainable operations during the next 3 years (agree fully 20,69%, agree partially 44,83 %).

4.5.10 Motivation of Colleagues to Improve Sustainability of the Company

Evaluated statement: "*I believe my colleagues will be motivated to improve sustainability of our company."*

A vast majority (86,21%) of representatives of medical device manufacturers based in Finland are confident and either agree fully (31,03%) or partially (55,17%) that they believe that their own colleagues would be motivated to improve sustainability of their company. About 10% (10,34%) partially disagree with the given statement and 3,45% do not know or consider it to be relevant. Nobody disagrees fully. (Figure 41)

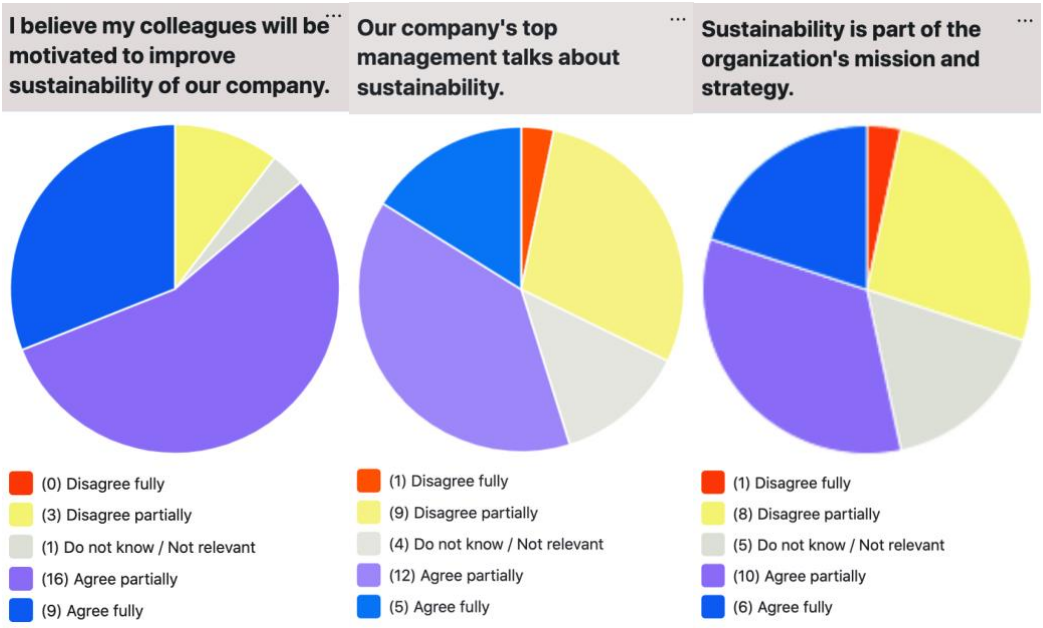

Figure 41: Medical device industry representative's views on whether their colleagues are motivated to improve sustainability of the company. Compared with: Division of views relating to top management communication and sustainability's role in mission and strategy.

This statement is the one where the strongest level of response alignment and agreement can be found. The full agreements imply that based on this sample, more than a quarter of the medical device professionals based in Finland would be strongly motivated to improve sustainability. The interpretation of partial agreements leaves space for interpretation. Do the results reflect commitment to improve the clinical value add, patient safety and data security but not necessarily much beyond that? Or commitment to certain aspects of ESG? Nevertheless, this answer provides insight that the professionals at medical device manufacturers based in Finland are sustainability aware and motivated to make improvements. Combined with the views regarding top management communication, mission and strategy, these results provide an outlook that sustainability changes at medical device industry will not only be top-down changes but that given the chance, the motivated professionals in this industry will be the driving force to implement missions and strategies in practise.

More detailed analysis of the results taking the company size into account reveals that the unconditional motivation is highest at large companies. Yet, however, regardless of the size of the organization, the motivation level of the industry

professionals to improve sustainability goes beyond what is currently set in the organizations' missions and strategies. (Figure 42)

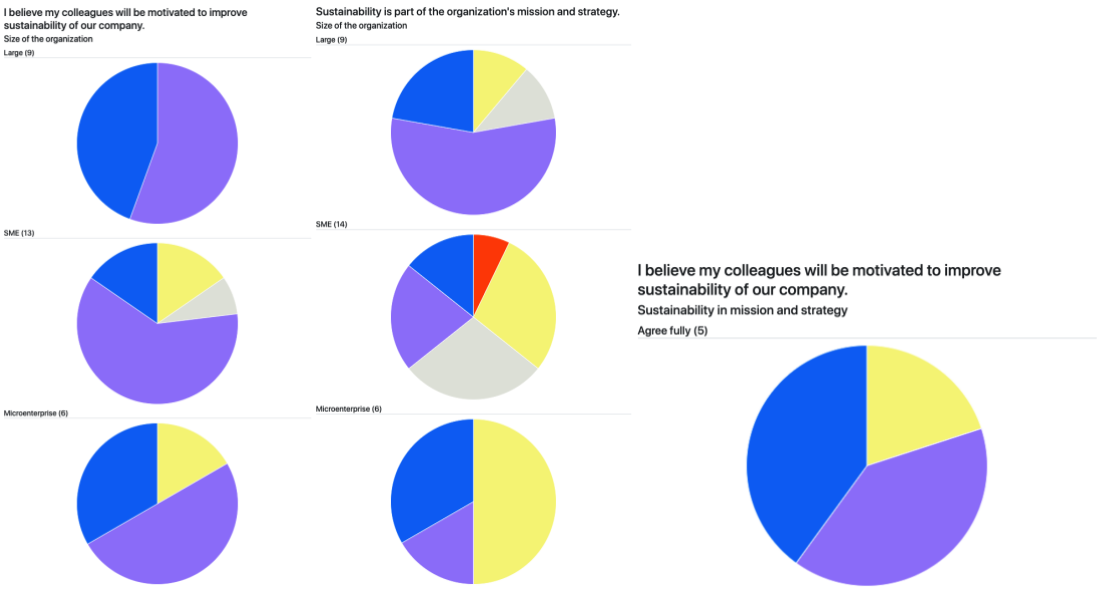

Figure 42: Detailed view on medical device industry representative's opinion on whether their colleagues will be motivated to improve sustainability of their company view of the results based on the company size. Compared with: Sustainability as part of strategy. Followed by: Detailed view of the results at companies with sustainability mission and strategy.

A clear bottom-up motivation to increase sustainability at medical device manufacturers based in Finland can be identified. This high motivation of the medical device industry based in Finland exists, irrespective of whether the medical device manufacturer currently has sustainability in mission and strategy, or not.

Summary: 86,21% of representatives of medical device manufacturers based in Finland either agree either fully (31,03%) or partially (55,17%) that they believe that their own colleagues would be motivated to improve sustainability of their company.

5 Conclusions and Discussion

While the Results and Findings chapter provided industry sample-based answers for the more precise research questions, this chapter focuses on the higher-level conclusions and discusses implications and meaning of the findings to medical device industry and healthcare in a wider context. Furthermore, ethical considerations, limitations of the research and areas for future research are identified.

5.1 CONCLUSIONS

Medical devices are critical elements of healthcare and impact directly sustainability of healthcare. Action research conducted in cooperation with Healthtech Finland investigated the views of quality and regulatory assurance professionals at large, SME and micro-sized medical device manufacturers based in Finland regarding the status of sustainability at their organizations. The artificial intelligence feature of the platform used to facilitate the data collection workshop for the industry professionals [129] summarizes one free format discussion. It identifies sustainability aspects raised by the industry representatives and quotes a thought-provoking statement that implies that despite claiming the importance of sustainability, many companies would still not take proactive role, but rather would do *"the bare minimum*". (Figure 43)

Figure 43: One AI based summary on comments given by representatives of medical device industry relating to sustainability.

The chapter complements and widens the AI based discussion summary by introducing and discussing the main conclusions. Further details and related references can be found in the Results and Findings chapter.

5.1.1 Medical Device Industry Sustainability Challenge

The sustainability challenge of the medical device is aligned with the challenges of the wider healthcare industry: reduction of environmental footprint, combined with need to support wider patient populations, while respecting equality. (Figure 44)

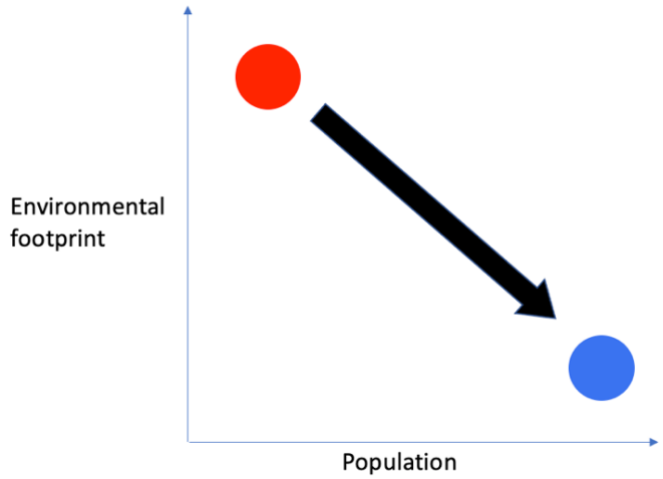

Figure 44: Medical device industry sustainability challenge

Healthcare has a significant environmental footprint size which has gained more attention during the recent years. Main challenge relating to reduction of environmental footprint is to find ways to implement the reduction while at the same time keep or increase the patient value and safety qualities.

While the social and ethical fairness of the operations of an organization and its supply chain are vital, from an impact perspective, key social sustainability challenges of the industry relate to availability and equality. According to World Health Organization (WHO), approximately half the world's population lacks access to essential health services. WHO promotes access to good quality, affordable and appropriate medical devices as means to address Universal

Health Coverage, health emergencies and support of healthier populations [130]. Regardless of increased global awareness, the challenge to develop and adapt health technologies for the needs of low-resource countries remains [131] [132].

Medical device manufacturers are the leading global experts of healthcare related technology with most advanced competences to address health and wellbeing needs of wider patient populations. Demand to invent ways to improve affordability of current solutions exits. More comprehensive contribution to the UN SDG3 health and wellbeing related targets would require medical device manufacturers also to use their competences and resources to address healthcare needs of wider, less privileged global audiences, particularly in low-resources countries. Unmet demands and global shortage of healthcare personnel propels the application of novel technologies including AI. This brings along novel equality related ethical questions that need to be solved in practice.

The governance frameworks at medical device manufacturers based on current regulatory requirements provide a stable platform, that with deliberate efforts can be expanded to support enhanced social sustainability, environmentally sustainable manufacturing and building of circular medical device lifecycles.

5.1.2 Differences in Strategic Importance

The research portraits a view of an industry where some medical device manufacturers have proactively taken initiative to include wider sustainability to their mission and strategy, at the same time many are operating under the strict guidance of industry specific regulations, with primary focus around clinical value, safety, and security. Based on the sample, 20% of the medical device manufacturers can be perceived sustainability leaders of the industry. These companies have sustainability in their mission and strategy and are ahead of the rest of industry in integrating sustainability into their operations. They, for example, pay attention to sustainability of their own suppliers (Figure 45) and are more confident in the level of in-house sustainability competence than their peers.

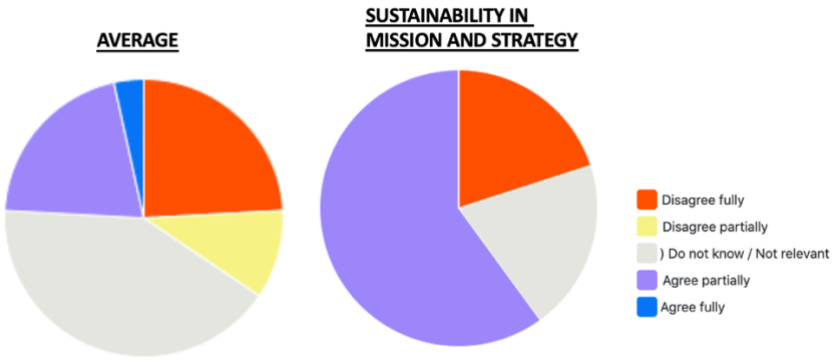

Figure 45: Example: Division of views relating to validity of statement: “Supplier's sustainability is a selection criterion and ESG performance is systematically monitored.” The difference in views of the industry sample average responses versus responses of companies that have sustainability in mission and strategy.

On average, the results also show that large medical device manufacturers have sustainability in their mission and strategy more often than their smaller peers. However, the research also reveals that also some microenterprises are sustainability thought leaders.

5.1.3 Sustainability beyond Industry Specific Regulatory Compliance

The chosen perspective of the research was to approach the sustainability theme from the inside industry point of view. This was reached by taking the current regulatory requirement-based practises of the industry as the starting point and asking medical device industry professionals to provide their views on how selected sustainability impact related practical indicators are applied at their organizations. The multiple-choice exercise was complemented with opportunities to provide free format text input. The research outcome, detailed in Results and Findings chapter, indicates that medical device manufacturers based in Finland have a desire to become more sustainable. However, the results also imply that sustainability considerations beyond current strict industry specific regulatory requirements are on average not widely applied with the medical device industry and many medical device manufacturers’ operations and resources remain strongly geared towards maintaining compliance with industry specific demanding regulative requirements.

Figure 46 uses color-coding to visualise the mode, the most popular answer option of the medical device industry representatives relating to each given sustainability related statement. The figure provides a very generalized overview, lacking the necessary more comprehensive insights available in chapter Results and Analysis. Figure 46 uses the same colour codes as used earlier in the report (blue for fully agree, purple for partially agree, grey for do not know or not relevant, yellow for partially agree and red for fully disagree). One cross-control question relating to separate sustainability strategy has been excluded from the figure.

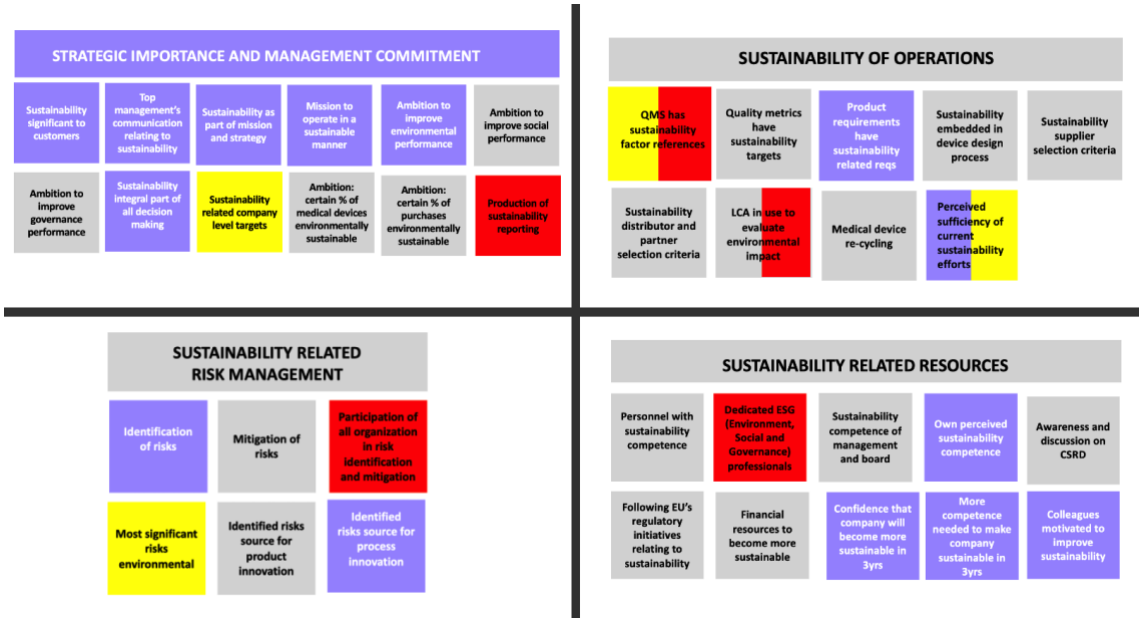

Figure 46: A color-coded visualisation the most popular answers relating to given sustainability statements.

This input overview visualises that sustainability is most prominent in strategic level among the medical device manufacturers based in Finland, complemented by personnel's strong confidence in sustainability transition and motivation to contribute to it. These medical device industry sustainability drivers are discussed in more detail later in this chapter.

It is to be noted, that Figure 46 can be misleading as it highlights the "do not know" or "not relevant" answers provided by industry representatives. Even if "do not now or not relevant" option may have been the single most selected option,

in many cases, majority of answers are distributed between different levels of agreement and disagreement.

The snapshot, however, visualises that the participants of the research, the quality and regulatory assurance professionals at medical device manufacturers, are not currently widely involved or aware of sustainability related efforts within their organisation. Thus, based on this industry sample, sustainability is not perceived to be closely linked to medical device manufacturer's quality or regulatory assurance but rather considered as separate competence area. This interpretation is confirmed by the participant feedback at the end of the interactive workshop; 67,86 % of respondents considered the workshop to be useful but not in their focus right now, 14,28% found the theme not relevant to their work and 17,85% considered the content very useful and topical to their work.

Considering the quality and regulatory assurance professionals' general high level of awareness of the status of operations within the organization, the fact that "do not know or not relevant" answers represent the most selected answer option, implies that sustainability, beyond the industry regulative requirements, would not currently be widely implemented in the operations. Furthermore, as "agree fully" is in no case the most popular option, Figure 46 implies, that evaluated statements are not widely applied in the industry on average. The snapshot plays a picture of an industry that on average has not yet taken a very proactive role to drive sustainability but rather responds to current customer and regulatory requirements. Again, as stated earlier, Figure 46 does not visualise that companies' situations may differ strongly from the view provided by this figure. Results and Findings chapter provides complementary insight that despite the overall early-stage maturity, also sustainability forerunners can be found in this industry.

5.1.4 Medical Device Industry Sustainability Deployment Gap

The research reveals a Sustainability Deployment Gap between the current situation and situation where medical device industry contributes as a key enabler to sustainable healthcare.

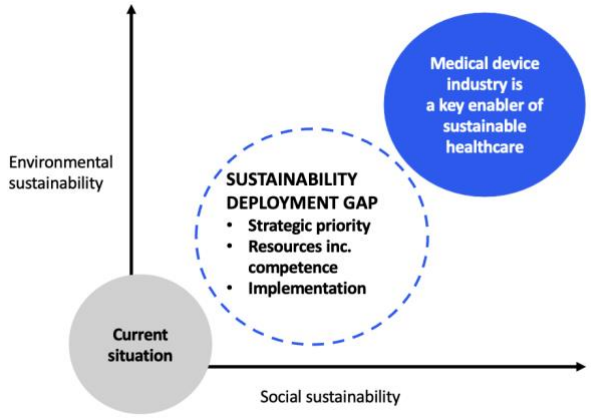

Figure 47: Medical Device Industry Sustainability Deployment Gap

Based on the answers provided by medical device industry professionals, on average, the recognised interest in increased sustainability has not led into wider scale operative implications. This is also the situation in case of sustainability related risk management. Results and Findings chapter provides several examples that wider people and planet considerations that go beyond patient safety, are not extensively deployed in the processes and policies according to which the medical device manufacturers operate, nor in the product specific requirements.

Despite the management and personnel interest in sustainability, it has not been granted high enough strategic priority so that it would impact operations in practice e.g., company level targets. The level of deployment is also closely linked to the level of available resourcing and sustainability related competence. Medical device industry professionals identify the need to increase awareness and learn new sustainability related knowledge and skills during the coming years. It will be a collaborative learning process, and the respondents point out

that also the board and management of their organizations need to deepen the knowledge and understanding in this area.

The Sustainability Deployment Gap is, to a large extend, caused by the substantial regulatory requirements that currently impact the operations of medical device manufacturers. The downside of the patient safety geared regulations is that device development cycles are resource consuming and long. The sustainability deployment gap is partially also caused by the mindsets. Instead of welcoming a challenge to find new and different ways to operate, sustainability can be perceived as set of additional requirements that have undesirable impacts including delayed development and increased costs. Existence of a sustainability deployment gap is not unique for this industry. On a global scale, sustainable practices, in general, lag behind the commitments.

5.1.5 Medical device industry Sustainability Drivers

The research identifies drivers that push medical device industry towards increased environmental and social sustainability. These drivers include prominent, rising customer interest, proposed sector agnostic EU sustainability regulations, management interest and motivated personnel. (Figure 48)

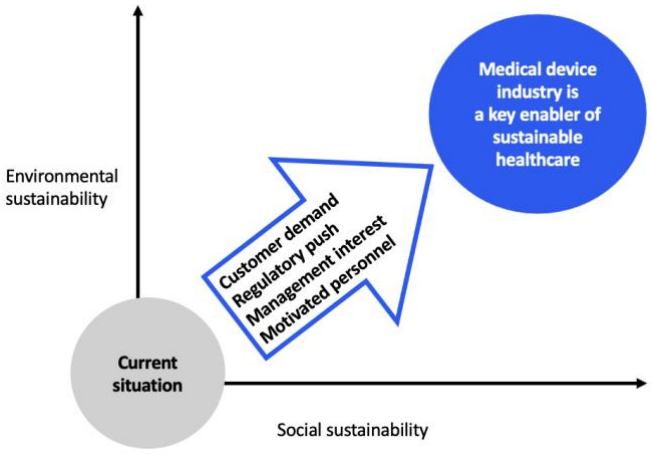

Figure 48: Medical Device Industry Sustainability Drivers

Customer needs and regulatory requirements have traditionally been drivers for this industry and the research highlights clear indications that both these external drivers are pushing towards increased sustainability. Based on the results, further two internal drivers that complement each other can be identified: management's awareness and the personnel's even stronger interest and confidence to contribute to more sustainable operations. Professionals working for medical device manufacturers based in Finland send a strong message that they are confident that their companies will make a transition towards more sustainable operations within the next three years and that the personnel are motivated to contribute to making the companies more sustainable. This is significant as the contribution of the industry professionals is in a fundamental role in delivering on the strategic commitments in practice.

5.1.6 Sustainability Impact Potential of Large Companies

Global medical device industry is polarized. With higher global market share and stronger resourcing, the large global companies have enhanced opportunities to contribute to wider scale global impact. Based on this research findings large manufacturers are in many cases ahead of their smaller counterparties, yet they still can improve in many ways e.g., in the level wider range of sustainability related requirements are included into the product requirements. Reduction of environmental footprint of large manufacturers will push reduction of environmental footprint of the healthcare industry. Similarly, larger actors in medical device industry have potential for larger handprint: larger scale positive ecological, economic, and social sustainability impacts. European Union recognizes this influence power of large companies to impact broader society besides the immediate stakeholders, and large companies are the ones impacted first by proposed EU level sector agnostic sustainability reporting requirements. SMEs are on the other hand, in general, known for their agility and innovation power, both qualities that are required when driving change.

5.2 DISCUSSION

5.2.1 Limitations of the Research

Sustainability is a wide concept and as the research question addresses the need for an industry specific status overview, the research scope becomes wide. As discussed in the Research Question chapter, forming an overview of the industry status has its value, but downside of a wide scope is that the research output stays on a high level. While high-level results serve a wider audience, they lack the necessary detailed perspectives required for operative execution. Thus, the research results are in optimum case to be used in combination with complementary more specialized research results and other information sources.

The second set of identified limitations relate to the sample used in the research. One may question whether the companies that participated in the workshop provide a representative sample of medical device manufacturers based in Finland. A different sample could have possibly resulted in a different outcome. The research, tailored to serve the medical device manufacturer needs, was a first of its kind. There was no historical data or data from other markets or industries with which the results could be compared. A larger sample size would have increased the reliability and validity of the results. The results were also impacted by the role of the professionals that provided the input. Accustomed to audits, quality and regulatory assurance professionals are particularly meticulous to base all views on evidence data only.

The research data collection method used, consisting primarily of multiple-choice input, can be perceived as a limitation. Similarly, the fact that respondents could see other participants answers and had the opportunity to change their own answers freely may be considered as a limitation. The results and findings of the research, however, do not suspect that seeing input from other companies led to situation where responses were “improved” based on answers of others. Instead, the responses demonstrate common motive to gain an honest view of the industry status.

As noted in Results and Findings chapter, interpretation of the given results was not always straightforward as respondents were not asked to provide reasoning for their choices. The survey design choice, to cover multiple topics versus to focus on deep insights of limited number of topics, was based on two reasons: 1) to make the data collection experience smooth and effective and 2) to collect efficiently wide range of information to answer the wide research question. The sections with free text input, and analysis of results conducted by the industry representatives complement slightly this limitation. Ultimately, the analysis is based on industry insights and background research including the listed reference material. More details on noticed limitations and result interpretation difficulties are included in chapter Methods and Data chapter, as well as in chapter Results and Findings.

Whereas the analysis included in the Results and Findings chapter includes more detailed analysis of companies that have sustainability in their mission and strategy, as well as analysis based on company size, the research analysis does not analyse individual companies one by one. Such even more detailed analysis could have provided even deeper insights of the industry status. The analysis takes into account public information of a few organisations, but the research does not include a systematic extensive analysis of public material of medical device manufacturers based in Finland. Theme interviews relating to the research were limited to background research phase and contributed to the formation of the survey content. The chosen method produced a wide scale output with prevalence indications that are important for a status overview, however, industry representative interviews could have provided deeper insights that the chosen method did not produce.

A key limitation of a status overview is that the information may get outdated in a relatively in short timeframe. However, the wider contribution explored more in sections Contributions to Industry and Contribution to Research, may have longer term value.

5.2.2 Ethical Considerations

Medical Device related Ethical Considerations

Sustainability as a topic is closely intertwined with ethics. Sustainability decisions are ethical decisions making them more challenging than technical decisions based on performance and other more straightforward criteria. Medical device manufacturers make multiple patient safety related ethical decisions. The regulatory requirements and governance by Notified Bodies and national authorities oversee the patient related ethical decisions made by medical device manufacturers for the protection of the patients. In that sense, as medical device industry “documents everything”, the ethical decisions are under more scrutiny than in most other industries. The industry can overall be perceived to be compliancy driven as the products market access and therefore the whole business is extremely dependent on regulatory compliance.

Whereas the industry excels at compliance, some of the more complex sustainability decisions of medical device manufacturers go beyond compliance and are business decisions. By default, medical device manufacturers contribute to health and wellbeing by producing vital solutions that enhance life quality and / or sustain life. Complementing the public research and leading clinical research and development efforts that in a long run may benefit wider global audiences also have significant social contribution value. The key ethical question of the industry is to what extend doing good in one area entitles ignorance or negative impact in others? The research reveals that e.g., environment related considerations and related ethical decisions are currently not common in the operations of the medical device manufacturers. The key focus is on the patients and healthcare professionals. This is also reflected in the mindset that is more of a manufacturer or a supplier versus having a wide ethical ownership of the device throughout its lifecycle. It is also less discussed to what extend the medical device industry can be perceived socially sustainable if it does not address the needs of the whole global population but rather focuses on the most privileged part of the global population.

The ethical responsibility of private sector is a complex topic. Health of a population is key to its ability to function. Whereas global healthcare has both public and private providers, the medical device industry is run by the private sector. In the EU, industry specific regulations to a large extend specify how medical device manufacturers need to operate. In capitalism, companies can be incentivized to address public needs but as far as they act according to regulatory requirements, they ultimately choose their own focus without externally set responsibility to contribute to solving any global challenges. As a result, enterprises primarily aim to sustain and grow their operations and provide value for chosen customer markets. Solving global problems beyond that is in most cases out of scope and perceived resources of the companies. Overall, the topic is complex and related ethical questions are not widely discussed within the industry in the context of social sustainability and responsibility.

More prominent ethical decisions that medical device manufacturers face relate to usage of data and artificial intelligence. In addition to the more discussed patient equality related issues relating to AI based or AI assisted decision-making, one medical device industry representative raised a less discussed concern: "*Before artificial intelligence solutions are started to being fully utilized, there should be thorough ethical and sustainability discussion. Is there a risk that the use of high technology makes us more dependent on technology and perhaps could degrade some professional skill (think of what navigators and navigation maps did to common people's map using and orienteering skills)?"*

Research related Ethical Considerations

Conducting the research also raised several ethical considerations. The research question and answers to it are wide and complex and therefore generalisations bring along danger of misleading the readers and thus impact their sustainability related decision making. Wide transparency to the results (already during the workshop and in this report) as well as to identified limitations aim to enable the readers also to independently make other conclusions based on the results of the

research. Sustainability theme brings along challenges to remain objective e.g., in the selection of references used. Research conducted by one person results in all cases in an outcome that is unavoidably impacted by the individual. The analysis, conclusions and discussion involve personal interpretations of what is fair representation of the wide scale of results and findings. To address this limitation, the research intentionally aims to provide high transparency to the results.

The Introduction and Research Question sections of the report deliberately communicate that the chosen approach, action research, has an objective to activate the target audience. Despite the efforts to stay neutral, it can be questioned, to what extend a sustainability researcher can stay objective versus how much the desire to impact the sustainability development interferes with objectivity of the researcher or researchers in this area, in general.

The researcher has background in medical device industry, understanding of which benefits this research. During the research, she was not employed by medical device industry and therefore can be perceived independent. However, the fact that the research is conducted in cooperation with Healthtech Finland, a non-profit industry association, may introduce concerns relating to whether the research can be objective. To secure an objective view, the approach in the research is to use transparency. For the sake of record, it is to be noted that no renumeration was received from Healthtech Finland for the research and Healthtech Finland was not involved in the design of the survey, analysing the results, or writing the report. The research aims to provide transparency that can benefit the medical device industry and healthcare in global scale, to implement efficiently measures that positively impact sustainability of the operations, and therefore contribute to addressing the massive global sustainability challenges.

The essence of the research are the insights provided by the medical device industry professionals based in Finland. Their authentic contribution reflects understanding of the complexity of the sustainability theme and that sustainability initiatives may also turn out to be counterproductive. One participant pointed out:

"Greenwashing in the name of improvement may lead to reversed development and waste of resources." In general, the research participants' input does not necessarily portray their employers to be as advanced in their sustainability measures as the organizations might desire. This differs from current general business communication style that highlights desired strengths and does not offer this level of transparency to operations. The research provided safe means for the medical device industry representatives to share views and therewith take the whole industry forward. During the workshop, not all workshop participants chose to actively contribute with answers but instead selected to passively follow the workshop. Therefore, even the participants of the online workshop themselves do not know which organisations contributed to the research.

5.2.3 Contribution to Industry and Research

Contribution to Industry

The primary contribution of the research is that it highlights the significant role medical devices have on the sustainability of healthcare, and on solving global challenges, particularly those relating to health and wellbeing. The research raises awareness of the urgency to contribute to solving sustainability challenges and highlights that all medical device industry professionals, regardless of their role, can make an impact by having wider people and planet considerations when making daily decisions.

The background research, industry tailored sustainability status evaluation framework and analysis of the results, can shorten individual professional's sustainability related learning curve and bring efficiency gains for organizations to plan and implement organisation specific actions. The Sustainability Deployment Gap detailed in Results and Findings chapter, provides examples of areas, addressing of which may directly contribute to enhanced sustainability of operations. The research recognises that having robust and traceable processes, the medical device industry is well positioned to roll out new requirements and practises.

The research provides an understanding of the status of sustainability of the industry but also underlying reasons. In addition to the analysis made by the researcher, the technical implementation of the survey involved the industry professionals themselves to analyse some of the results. The free text format quotes introduce unedited genuine views of professionals working for medical device manufacturers based in Finland. The overall results may not come as a surprise for industry professionals, yet sustainability themes included in the research and visibility to the industry samples' views may contribute to new ideas and actions.

The research framework indicates that regardless of the role, a single professional in the industry can, in daily decisions and actions, contribute to enhanced sustainability. In addition to offering an industry tailored framework to map the status of sustainability of operations, the research contributes to comprehension of the significance of having sustainability integrated in the mission, strategy, and values of the company. The research challenges the medical device industry to not settle on addressing sustainability as compliance driven tactical "box checking" exercise but rather to move beyond the compliance mindset to systematic work towards strategic aspirational goals with sustainable impact.

Proposed EU regulations aim to increase quality, reliability, transparency, and comparability of also social sustainability statements made by companies used for decision-making by different stakeholders including investors and customers. While the financial drivers will remain, and are essential for vitality of private companies, the research highlights signs of clear change in general value landscape in the healthcare industry, which are further supported by the developments in the EU regulation. The research provided indications that in addition to sustainability of a medical device manufacturer being important to their

customers, also professionals of this industry are motivated to increase sustainability of the operations and the devices.

The operative Sustainability Deployment Gap and level of sustainability related competence at the medical devices, encourages co-learning and closer cooperation with healthcare service providers. As the medical devices environmental footprint to large extend materialises at the usage stage and stages following that, closer co-creation has opportunities to expedite both learning and innovation of all parties involved. Ultimately, a common goal: a status where sustainable medical devices are key enablers of sustainable healthcare, can be reached.

A side benefit of the research, not initially intended in the planning phase, is the value for wider healthcare industry and policy makers by increasing understanding of the medical device industry. Without industry inside experience, it can be challenging to comprehend the extend and overarching impact the medical device related regulations have on the manufacturers and how adding any further regulations in addition to the existing ones can threaten the vitality, innovation and even existence of particularly the small and medium size medical device manufacturers. The matter is not trivial as 95% of European medical technology companies are SMEs. These companies, many times with strong links to publicly funded research, have an important role in introducing new solutions and ways of thinking to address the needs of healthcare. It would be an enormous loss if increased sustainability awareness would lead to situation where SMEs cannot keep up with external requirements and end up either being acquired by larger companies or need to cease operations. The European Union seems to comprehend that Europe cannot afford to lose the innovation power and social contribution of SMEs and thus sustainability related regulative initiatives are initially directed towards large companies. However, as all companies operate in the same economy, the concern remains.

The above does not mean that small and medium sized medical device manufacturers could not be leaders relating to sustainability. But is it more

demanding if sustainability is perceived as “yet another additional set of regulatory requirements” that needs to be complied with, “on top of the current requirements”, and “in addition to the actual business”. From such a viewpoint, sustainability can become a heavy burden that eats up valuable scarce resources. The outcome created by random, minimum possible efforts may also turn out to be unavailing. However, as the outcome of the research indicates, if the mission and values of the company are sustainability aligned, wider people and planet considerations can become the norm in the operational strategy execution. This does not necessarily create overload but rather changes the current processes. For example, an even closer cooperation with customers in the design phase with the aim of reducing the environmental footprint may lead to multiple other benefits, also clinical and economic.

Medical device manufacturers are used to a situation where regulations compliance needs to be reached before being able to bring their products to the market. By introducing practical examples that are meant to be relatively straightforward to integrate into the current processes of medical device manufacturers, the research provides means to take small steps to increase sustainability of operations. The approach of planned future EU regulations acknowledges that no such thing as reaching sustainability compliance, exits. The aim by the regulations is that companies would provide increased transparency to the status of sustainability and on the continuous progress made towards desired direction. And then, ultimately customers and investors would be in a position to invest in companies that operate and want to operate in a sustainable manner. If a company already operates sustainably, communication and reporting about that is not a major burden. The research highlights some differences between the survey output and public information of a couple of large medical device manufacturers and customers.

The research contributes to the culture in which professionals in medical device industry share sustainability related knowledge and best practises. No organization can alone solve the global sustainability challenges. Nobody wins if sustainability innovations are patented and kept as property of single companies.

Besides industry cooperation in this area, strategic alliances between parties in high-income and low- or middle-income countries can increase contextual awareness [132] . Through cooperation, whole industries, such as healthcare, can make major leaps towards increased sustainability.

Medical device manufacturers have a firm basis to reach a status where sustainable medical devices are key enablers of sustainable healthcare. At the heart of this are the disciplined processes and mission driven professionals who already have chosen to work for an employer that makes a positive social impact, and who based on outcome of the research have high level of motivation to contribute to increasing sustainability of their companies. Change does not happen automatically but requires deliberate prioritization of sustainability by the owners and management, combined with deliberate efforts of individual professionals to continuously seek ways to enhance the sustainability of the operations of not only their own company but their customers. Whereas, the research provided understanding of industry status, each organization needs to form, in dialogue with its interest groups, understanding of the sustainability status of the organization, what impact the organization currently makes, and based on that identify development areas. One workshop participant summarized this need as follows: *“Investigate and evaluate the preparedness of company's sustainability operations.”*

By contributing to the research, the medical device manufacturers based in Finland offered transparency to the status of sustainability of medical device manufacturers that has not been available earlier. The research can benefit medical device manufacturers and healthcare operators, not only in Europe, but globally, when taking deliberate steps towards a situation where sustainable medical devices are key enablers of sustainable healthcare.

Contribution to Research

As there was no earlier information available on the research question, it would be valuable that this research would inspire future research on the same theme.

Further research that addresses the limitations of this research could bring clarifications or challenge the findings and conclusions of the research. Systematic follow up, comparing the results of 2022 with results of later years, would visualise the progress that the companies are, based on the findings of the research, expected to make in this area during the coming years. Medical Device Industry Sustainability Challenge as specified in the Conclusions section of the report highlights two key areas which would be interesting to research further: The reduction of environmental footprint of the industry and the initiatives to increase the patient population reached by medical devices. Furthermore, demand for further research on learnings of medical device manufacturers who have taken measures to solve diverse SDG3 targets can be identified, to discover best practises to address wide range of SDG3 targets, and to increase global access to medical devices particularly in low-resource countries.

When a research question approaches a complex wide theme, the answers also raise multiple new questions. Hence, the content of the research can inspire further research in multiple areas. As this is a status overview, it covers only certain topics. The research may inspire research on more specific industry specific sustainability topics that are important but were completely ignored in the research e.g., status of anti-corruption and employee equality in the medical device industry. Similarly, further research can investigate further particular topics that were merely touched on a high-level e.g., integration of sustainability requirements in the product requirements and design process, or impact of circularity and new related business models to medical device manufacturers and particularly to their customers. Research focusing on application of artificial intelligence in medical devices from the ethics and equality perspective is also necessary.

In general, as this is a status focused research, an area of interest for the medical device industry would be research on industry specific means and measures to address the identified Sustainability Deployment Gap, and effectiveness of such measures. Such could include research on how companies choose to bridge the gap between strategy and operations e.g., by setting objectives and desired key

results or measuring and analysing the internal and external impact of changes implemented in the processes. In general, also future related research that would go further into the future and various global health scenarios and role of medical devices and competences needed, would benefit healthcare industry.

The research was conducted with an industry sample consisting of medical device manufacturers based in Finland and as such can be used as contribution to industry specific similar research in other countries. With the direct linkage to sustainability of healthcare, the research contributes to research on sustainability of healthcare industry supply chain. Approaching the same topic from the customer angle would most probably provide some very interesting new insights. In addition to application of this research in healthcare industry, learnings from this industry and the approach taken, can also be applied to sustainability research of other industries. Such learnings include e.g., approaching the sustainability research from the industry inside point of view and / or usage of advanced communication platform in a workshop setting in the data collection phase of action research.

Status research looks backwards, whilst it is vital to look forward. The value of this early-stage action research to the research community will ultimately be measured on how medical device related sustainability research will increase and develop from its current state, and to what extend aforesaid research impacts the operations of medical device industry in practise.

6 References

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Appendix 1: Impact Assessment on UN Sustainable Development Goals (SDGs)

Which UN Sustainable Development Goals your organisation contributes to?

0 Do not know

1 Direct negative

2 Indirect negative

3 No impact

4 Indirect positive

5 Direct positive

Round 1 - (21 answers)

	Average
Goal 1: End poverty in all its forms everywhere	2.9
Goal 2: End hunger, achieve food security and improved nutrition and promote sustainable agriculture	3
Goal 3: Ensure healthy lives and promote well-being for all at all ages	4.2
Goal 4: Ensure inclusive and equitable quality education and promote lifelong learning opportunities for all	3.3
Goal 5: Achieve gender equality and empower all women and girls	3.1
Goal 6: Ensure availability and sustainable management of water and sanitation for all	2.8
Goal 7: Ensure access to affordable, reliable, sustainable and modern energy for all	2.9
Goal 8: Promote sustained, inclusive and sustainable economic growth, full and productive employment and decent work for all	3.1
Goal 9: Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation	3.4
Goal 10: Reduce inequality within and among countries	3.2
Goal 11: Make cities and human settlements inclusive, safe, resilient and sustainable	3
Goal 12: Ensure sustainable consumption and production patterns	3.2
Goal 13: Take urgent action to combat climate change and its impacts*	3.1
Goal 14: Conserve and sustainably use the oceans, seas and marine resources for sustainable development	2.9
Goal 15: Protect, restore and promote sustainable use of terrestrial ecosystems, sustainably manage forests, combat desertification, and halt and reverse land degradation and halt biodiversity loss	2.8
Goal 16: Promote peaceful and inclusive societies for sustainable development, provide access to justice for all and build effective, accountable and inclusive institutions at all levels	3
Goal 17: Strengthen the means of implementation and revitalize the global partnership for sustainable development	3
Total average	3.1

Appendix 2: Impact Assessment on SDG3 Targets

What kind of impact your organisation has on the Good Health and Wellbeing targets?

0 Do not know

1 Direct negative

2 Indirect negative

3 No impact

4. Indirect positive

5 Direct positive

Round 1 - (27 answers)

	Average
Target 3.1: By 2030, reduce the global maternal mortality ratio to less than 70 per 100,000 live births	3
Target 3.2: By 2030, end preventable deaths of newborns and children under 5 years of age, with all countries aiming to reduce neonatal mortality to at least as low as 12 per 1,000 live births and under-5 mortality to at least as low as 25 per 1,000 live births	3.2
Target 3.3: By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases	2.9
Target 3.4: By 2030, reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being	3.4
Target 3.5: Strengthen the prevention and treatment of substance abuse, including narcotic drug abuse and harmful use of alcohol	2.9
Target 3.6: By 2020, halve the number of global deaths and injuries from road traffic accidents	2.7
Target 3.7: By 2030, ensure universal access to sexual and reproductive health-care services, including for family planning, information and education, and the integration of reproductive health into national strategies and programmes	2.7
Target 3.8: Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all	3
Target 3.9: By 2030, substantially reduce the number of deaths and illnesses from hazardous chemicals and air, water and soil pollution and contamination	2.9
Target 3.a: Strengthen the implementation of the World Health Organization Framework Convention on Tobacco Control in all countries, as appropriate	2.7
Target 3.b: Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all	2.9
Target 3.c: Substantially increase health financing and the recruitment, development, training and retention of the health workforce in developing countries, especially in least developed countries and small island developing States	3
Target 3.d: Strengthen the capacity of all countries, in particular developing countries, for early warning, risk reduction and management of national and global health risks	3.3
Total average	3