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Elisa Sipola

Usability engineering of medical devices

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Elisa Sipola

Usability engineering of medical devices

In 2017, regulation on medical devices has been refined by new European medical device regulation (2017/45). Compared to the previous medical device directive, the reforms emphasize the usability of the devices, which is partly explained by the emphasis on risk management. The reform aims to increase the patient and user safety of the device. According to the regulation, manufacturer must be able to confirm that the medical device meets the general safety and performance requirements. Usability requirements have been previously confirmed as a part of product validation. With the reform, usability engineering documentation must be created.

The aim of the thesis was to compile essential standards for demonstrating compliance with requirements of the medical device regulation. In addition, the intention was to create user specification documents for two product families.

The essential standards were compiled based on the requirements of medical device regulation and documents was created by utilizing commonly used standard and the company’s earlier created documents. The topicality of the documents was critically assessed. Furthermore, development ideas were found for the use and exploitation of the created documents.

Keywords:

medical device regulation, usability engineering, risk management, usability

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Elisa Sipola

Lääkinnällisten laitteiden käytettävyyden suunnittelu

Lääkinnällisiin laitteisiin kohdistuvaa sääntelyä on tarkennettu uudella eurooppalaisella lääkintälaiteasetuksella vuonna 2017 (2017/45). Verrattaessa aikaisempaan lääkinnällisten laitteiden direktiiviin, uudistusten myötä laitteiden käytettävyys korostuu, mikä selittyy osin riskienhallinnan korostumisella. Uudistuksen myötä pyritään lisäämään laitteiden potilas- sekä käyttäjäturvallisuutta. Asetuksen mukaan valmistajan on pystyttävä todentamaan, että lääkinnällinen laite täyttää yleiset turvallisuus- ja suorituskykyvaatimukset. Käytettävyyteen liittyvät vaatimukset ovat pystytty aikaisemmin todentamaan osana tuotevalidointia. Uudistuksen myötä on luotava käytettävyysdokumentti.

Opinnäytetyön tavoitteena on koota olennaisia standardeja lääkintälaiteasetuksen vaatimusten täyttämisen osoittamiseksi. Lisäksi tarkoituksena on luoda käytettävyysdokumentti kahdelle tuoteperheelle.

Olennaiset standardit koottiin lääkintäasetuksen vaatimusten pohjalta ja dokumentit luotiin yleisesti käytettyä standardia hyödyntäen. Dokumenttien sisältö luotiin yrityksen aikaisemmin luotujen dokumenttien pohjalta. Dokumenttien ajankohtaisuutta arvioitiin kriittisesti. Lisäksi luotujen dokumenttien käyttöön ja hyödyntämiseen löydettiin kehitysideoita.

Asiasanat:

lääkintälaiteasetus, käytettävyyssuunnittelu, riskienhallinta, käytettävyys,

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List of abbreviations

Hazard	Potential source of harm (IEC 14971:2019 p. 9.)
Hazardous situation	Circumstance in which people, property or environment is or are exposed to one or more hazards (IEC 14971:2019 p. 9.)
Intended use	Use for which product is intended according to specifications, instructions and information provided by manufacturer (IEC 14971:2019 p. 9.)
Life cycle	Series of all phases in the life of a medical device from the initial conception to final decommissioning and disposal (IEC 14971:2019 p. 9.)
MDCG	Medical device coordinator group
MDR	Medical device regulation
R&D	Research and development
Post-production	Part of a life cycle of the medical device after the design has been completed and the medical device has been manufactured (IEC 14971:2019 p. 9.)
Usability engineering	Knowledge about human behavior, abilities, limitations and characteristics in the designing process of medical devices, systems and tasks (IEC 62366-1:2015.)
Use error	User action or lack of user action while using the medical device that leads to different result than intended by the manufacturer or expected by the user (IEC 14971:2019 p. 9.)

1 Introduction

Usability engineering is a tool to fulfill general safety and performance requirements which are included in new medical device regulation 2017/745/EU (MDR). In order to meet the general safety and performance requirements, harmonized standards, medical device coordinator group (MDCG) guidelines and other essential standard and guidelines are utilized.

MDR considers the manufacturer responsible for demonstrating the safety and performance of a device. To do that, the manufacturer is responsible for providing the appropriate instructions. There are medical devices ranging from surgical masks, injection needles, contact lenses patches, dry eye products and artificial joint implants to pacemakers. Therefore, it is a challenge to take into account the peculiarities in the legal text of all medical devices.

The thesis was commissioned by the medical devices manufactures Finnsusp. The company manufacturers eyeglasses, contact lens care products and dry eye products.

In this thesis, the instructions for demonstrating the safety and performance of contact lens care products and dry eye products were compiled from generally used standards. In addition, the use specifications for the products were made to confirm the usability of the device. Usability evaluation is emphasized caused by risk management process in new MDR.

As a result of the study, standards were compiled to the theory part. In addition, two documents specifying the interaction between user and medical device were created. The documents were evaluated based on the sources for the documents. Methods for utilizing the usability engineering process were considered as well as methods to facilitate access to wanted documents.

2 Finnsusp Ltd

Finnsusp Ltd is a Finnish privately owned family-owned business founded in 1978. Finnsusp Ltd develops and manufactures contact lens care solutions, eye care products and individual Free-form spectacle lenses. Furthermore, Finnsusp Ltd offers laboratory services and contract manufacturing to companies. (Finnsusp, 2022.)

All the research, development and manufacturing take place in Lieto, Finland employing around 50 people (Figure 1). In addition to sales on domestic market, Finnsusp’s products are exported to over 30 countries in Europe, the Middle East, South America and North Africa. (Finnsusp 2022).

Figure 1 Finnsusp's Factory in Lieto, Finland. (Finnsusp, 2022.)

The Lieto factory is divided into chemical and optics production facilities. Chemical production accounts for 85 per cent of the revenue. For that revenue, the sale of dry eye products covers 60 per cent. The total revenue of the company in 2021 was 1.6 million euros. (Lehtinen, 2022.)

3 Medical devices

The term ‘medical device’ refers to any instrument, apparatus, appliance, software or other article intended by the manufacturer to be used alone or in combination for specific medical purposes. Medical devices are intended for diagnosing diseases and other conditions. Other purposes of medical devices are treatment, mitigation, monitoring, prevention or prediction of disease, injury or disability. In addition, medical devices can be intended to use for investigation, replacement or modification of the parts of the human anatomy or of a physiological or pathological state or process. Medical devices can also be used to provide information by means of in vitro examination of specimens derived from the human body. (2017/745/EU, Article 2; Dhillon, 2011, p. 4.)

Medical devices may affect the structure of the body or any function of the body. However, medical devices are not the same as drugs even though the formulation of a medical device and a drug can be exactly the same. To separate medical devices from drugs, it is important to notice that medical devices do not achieve its principal intended action by pharmalogical, immunological or metabolic means in or on human body. Nevertheless, pharmalogical, immunological or metabolic means can be used in a medical device as an assist to achieve its principal intended action. (2017/745/EU, Article 2; Dhillon, 2011, p. 4; Tukes, 2022.)

All medical devices have to obey the same prime criterion: do no harm. With regard to the intended use of medical device, the medical device shall meet the general safety and performance requirements. To fulfill the general safety and performance requirements the medical device shall achieve the performance intended by the manufacturer. The medical device must be designed and manufactured in such a way that the suitability of the intended purpose is guaranteed during normal conditions of use. Furthermore, the device shall be safe and effective and cannot compromise the clinical condition and safety of the user or patient. The general safety and performance requirements take into account user safety and health or, where applicable, that of other persons.

Some devices cannot be used for clinical purposes without causing any harm. In the use of medical devices, it is important that the benefits of use outweigh the harm. Medical devices may constitute acceptable risks of harm if weighed against the benefits to the patient and compatible with a high-level of protection of health and safety. (2017/745/EU, Article 5 & Annex I; Ogrodnik, 2020, p. 18.)

3.1 Medical device classification

Medical devices are divided into four classes I, IIa, IIb and III. The classification takes account of the intended use of the manufacturer for the medical device, as well as the risks associated with the use of the device. Furthermore, classification depends on the life cycle of the device. In general, the higher the classification the more chance that the device could do some harm (Figure 2). (2017/745/EU, Article 1; Ogrodnik, 2020, p. 18.)

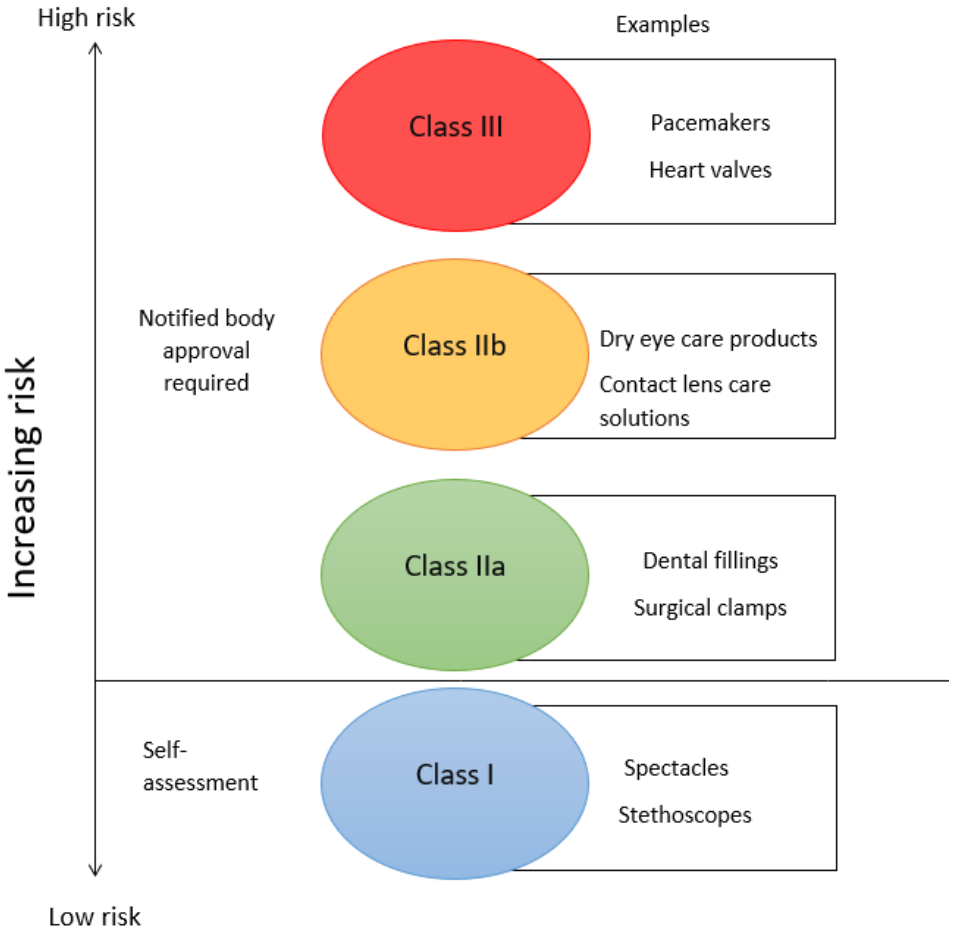

Figure 2 Medical device classification examples. (paraphrase Kerr-Peterson & Mulryne 2017.)

3.2 Classification rules

The classification is based on the risk for the patient. In the classification, the rules on the basis of which medical devices receive their class are used. It is essential to know the kind of the medical device. (Ogrodnik, 2020, p. 19.)

Invasive devices mean devices that are introduced in whole or in part into the body either through a body orifice or through the surface of the body. A body

orifice is any natural opening of the body, the external surface of the eyeball, or any permanent artificial opening, such as stoma. However, a device that administers energy to the body will not be invasive if only energy it emits penetrates the body and not the device itself. (MDCG, 2021-24.)

The first classification divides devices into invasive and non-invasive devices. Anything that is not invasive belongs to class I. The challenge of classification is the effects of the device properties. Classification is affected if the device is considered as an active device. An active device means a device whose function is based on energy sources that are not the energy generated directly by the human body for that purpose or by the gravity, and which works by changing the density of that energy. The invasiveness of the device and the duration of use also affect the classification (Table 1). Even an invasive device can be classified as I if the duration of use is transient. (2017/745/EU, Annex VIII; Ogrodnik, 2020, p.19; Pitkänen & al., 2020, p. 54.)

Table 1 Duration of use of the medical device.

Concept	Intended use
Transient	less than 60 minutes
Short term	between 60 min and 30 days
Long term	more than 30 days

The rules can be divided into four groups. Non-invasive devices comply with rules 1 to 4 and invasive devices comply with rules 5 to 8. Active devices and software must follow rules from 9 to 13 and the rest of the rules are for special devices. However, because the classification of rules takes into account many properties of the device, the device can fall into the definitions of multiple the rules of classification (Figure 3). (Ogrodnik, 2020, p. 19; Pitkänen & al., 2020, p. 54.)

RULES	CLASS I	CLASS IIa	CLASS IIb	CLASS III
1	•			
2	•	•		
3		•	•	•
4	•	•	•	
5	•	•	•	
6	•	•	•	•
7		•	•	•
8		•	•	•
9			•	•
10	•	•	•	
11		•	•	•
12		•	•	
13	•			
14				•
15			•	•
16		•	•	
17		•		
18				•
19		•	•	•
20		•	•	
21			•	•
22				•

Figure 3 Class in rule based on medical device properties. (paraphrase Ogrodnik, 2020, p. 20.)

4 Medical device regulation

In 2017, the European Parliament and Council issued a new regulation on medical devices, the MDR. The aim of the reform is to harmonize European regulation, improve traceability and increase patient safety. The MDR replaces previous directives on medical devices. According to the MDR, the manufacturer must be able to prove that products marketed in the European Union meet user requirements.

MDR defines common specifications as a set of technical and clinical requirements that provides a means of complying with the legal obligations applicable to a device, process or system, when no-standards do not exist or they are not sufficient. Common specifications may include general safety and performance requirements along with technical documentation. Furthermore, common speciation of a medical device may require clinical evaluation, clinical investigation, or post-market clinical follow up. The created documents shall be kept at the disposal of the authorities for at least ten years and submitted upon request of the authorities. The manufacturer is obliged to take corrective measures and is financially liable for compensation. (MDR, Articles 9 and 10; Pitkänen & al., 2020, p. 33.)

4.1 Risk management

Risk means a combination of probability of occurrence of harm and severity of harm. Risk management is a systematic application aiming to analyzing, evaluating, controlling and observing a risk. To manage risks, management policies, procedures and practices can be utilized. One of the general requirements of the MDR for medical devices is to reduce risks as far as possible. However, a benefit-risk ratio of the medical device cannot be compromised when minimizing the risks. Risk management can be applied to product development and as a cornerstone to an effective quality management system bringing pre- and post-market activities together. In addition, once the

product has been placed on the markets, the risk management system ensures the continuous safety and performance of the device. Functional risk management increases patient and user safety. To achieve the main purpose of risk management, the establishing, implementing, documenting and maintaining of the system is crucial. (MDR, Article 2; Pitkänen & al., 2020, p. 65; ISO 14971:2019.)

According to ISO 14971, an ongoing risk management process will include the following information, an identified hazard and hazardous situations that are associated with medical devices. Moreover, identified associated risks must be estimated and evaluated and risks must be in control. No risk management systems are efficient if the risk control effectiveness is not monitored. The process must apply throughout the life cycle of medical device. The process includes four elements that are risk analysis, risk evaluation, risk control and production and post-production activities. Individual elements have an emphasis depending on the life cycle of the medical device (Figure 4). (ISO 14971:2019.)

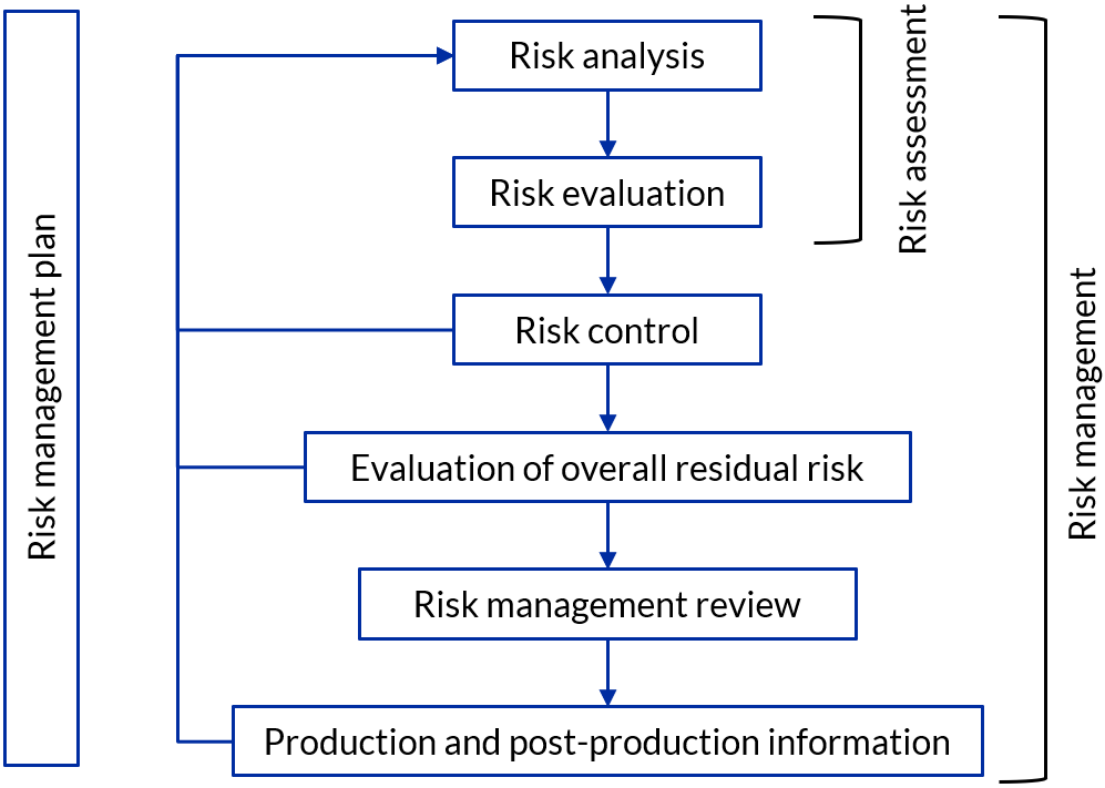

Figure 4 Stages of risk management. (ISO 14971:2019.)

A risk management plan is a tool for effective risk management. It is a requirement, because it ensures the sufficient organization of risk management, gives direction to risk management and prevents essential elements being forgotten. Furthermore, the plan enables objectivity. A well-planned risk management system includes a plan that takes note of the scope of the planned risk management activities and identifies the medical device and its life cycle phases. Each risk management plan element is applied to each phase in the life cycle of a medical device. A risk management plan should contain the assignment of responsibilities and authorities and requirements for the review of risk management activities. Creating criteria for risk acceptability must be included in the risk management plan as well. This means that the manufacturer must have a policy for determining acceptable risk based on the criteria even when the probability of occurrence of harm of risk cannot be estimated. Based on the manufacturer's policy for determining acceptable risk, a method to evaluate overall residual risk and criteria for the acceptability of overall residual risk must be created. Lastly, activities for the verification of implementation and effectiveness of risk control measures and activities related to collection and review of relevant production and post-production information have to be incorporated to the risk management plan. (ISO 14971:2019.)

Risk management is an iterative process. It starts from product development and continues throughout the entire life cycle of the medical device. Important input to the user requirements and consecutive product specifications is given at the initial risk management work, which can be made during product development. Risk management also gives a guide to the sufficient level of various efforts in the field of verification, validation and clinical evaluation. In the post-market phase risk management is of special importance. It can be utilized to analyze the impact of change to the device, in non-conformance situations as well as evaluating the need for re-evaluating production processes. An actively used risk management file during the post-market stage improves the ability of

the company to react if new hazards are recognized, in complaint handling and when considering possible vigilance actions. (Pitkänen & al., 2020 p. 66.)

4.2 Quality management system

The term ‘quality’ refers with a wide scale of meanings. Quality can be observed at consumer point of view when it can get determination based on user experience with the product or a service. It can be used as a strategic plan for company to get competitive advance. However, based on standard ISO 9000, quality is the ability of a manufactured product to meet consumers’ and other essential stakeholder’-s’ requirements. A quality management system is a way to ensure that the organization has defined its objectives and processes as well as resources needed to accomplish wanted quality. (ISO 9000:2015; Howarth & Watson, 2011. p. 2.)

MDR sets records to a quality management process. The manufacturer must actively document the manufacturing process to guarantee that the production of the device implemented within the terms of regulation. The quality management process must include the responsibilities of company management, resource and risk management, a clinical evaluation, production realization, the verification of unique device identification assignments and a post-market surveillance. Furthermore, the quality management system should include a process for monitoring and measuring outputs, documentation, analyzation and product development. There is a standard widely utilized in industry called ISO 9001. However, it is not specific enough for medical device manufacturers. Quality management system ISO 13485:2016 is typically utilized to complete the regulations. (MDR, Article 10; Pitkänen & al., 2020 p. 100.)

According to ISO 13485:2016 organization must have a documented quality management system. The quality management system should be maintained to the preservation of assertiveness. For building the quality management system processes that the quality management system requires need to be defined. The definition should include the applications of those processes in organization

taking into account the roles of the organization. Observing the process based on risks belongs to the requirements of quality management system too. Of these processes, mutual order and interaction needs the determination to fulfill the requirements. (ISO 13485:2016.)

Organization should have a procedure for every defined process of quality management system where criteria and methods of ensuring these processes significant actions and supervisor are noticed. In order to support this action, efficient resource management and communication is the key. Measures must be taken if necessary to obtain the planned results and maintain the effectiveness of the quality management. Processes should be monitored and analyzed when needed. The quality management system involves having documents to verify compliance with the requirements. (ISO 13485:2016.)

Even though, ISO 13485:2016 is developed for building a quality management system to the production of medical devices, it does not entirely achieve total conformity with the MDR by complying only with the requirements of the standard. Comparing the MDR and ISO 13485:2016, MDR requires incorporation of certain processes in quality management system, whereas ISO 13485:2016 requires the interaction of these processes in quality management system in accordance with regulatory requirements but does not include details the particular MDR within the standard. The listing of harmonized standards published on 17 May 2022, instructs to comply with ISO 13485:2016 and ISO 13485:2016/A11:2021 addendum to create and maintain a quality system. A11 is an addition made in 2021 to the ISO 13485:2016 standard. These must be followed in order to demonstrate that the quality system meets the requirements of the MDR. (ISO 13485:2016, Annex ZA.)

4.3 Conformity assessment

Conformity assessment is the demonstration that the specific requirements are fulfilled. The procedure should ensure the confidence of consumers, public authority and manufacturers regarding of conformity of products. The

manufacturer of the medical devices is responsible for produced products throughout the life cycle of the device. A work of a manufacturer does not end in placing the device on the markets. In reality, the life cycle of the device starts from that. In Europe, CE-marking is manufacturers insurance that the device completes the MDR. (Fimea 2021; IEC 17000:2020; Pitkänen & al., 2020 p. 64.)

A medical device must be suitable for its intended use. This considers the design, manufacturing, packaging and labelling of the device. Device must be suitable for its use under normal conditions. The device must be able to achieve the performance required by the manufacturer and does not compromise the clinical condition or the safety of the patients, users or other people. In order to do that, the medical device must meet the applicable requirements of MDR and the manufacturer must have an efficient quality management system. Hence, the compliance must be demonstrated from the product's perspective as well as the perspective of a quality management system. Conformity assessment includes three functions that aim to satisfy a need or a demand for demonstrating the specific requirements are fulfilled. (IEC 17000:2020; Pitkänen & al., 2020 p. 64.)

Selection involves planning and preparation activities that are used to collect or procedure all the information and input needed for following determination function. These collections or procedures includes a selection of the object for conformity assessment, specified requirements and the choice the most appropriate procedure for the conformity assessment. Finally, addition information can be necessary for insuring the effective fulfilled requirements. (IEC 17000:2020).

Determination activities are for collection and development for complete information regarding fulfilment of the specific requirements. Determination activities include testing, inspection, an audit, validation, verification and a peer-assessment. These are defined as a type of determination and can be used as a scheme to describe conformity assessment schemes which include the type of determination activity indicated. (IEC 17000:2020).

Final function to conformity assessment includes review, decision and an attestation. A review phase is a final stage to ensure the quality of conformity assessment before the decision of whether the object of conformity assessment has been reliably demonstrated to fulfil specific requirements. An attestation results in a statement of conformity. Certification, a declaration and accreditation are the types of attestation that can be used together with scheme to describe the conformity assessment schemes that include attestation activity indicated to final step. (IEC 17000:2020).

According to MDR, to conformity assessment, a manufacturer can make the declaration of conformity after twelve steps of conformity assessment process. A medical device must be defined for its intended use and classification. Identification of the requirements is needed for CE-marking. Identification is followed by the development of quality and risk management system also; a clinical evaluation plan must be created. After that, technical documentation can be created. Then the company must appoint a notified body in order to perform a quality management and the technical documentation audit. Audit is followed by conformity assessment, a declaration of conformity, a unique device identifier for the device and post-market surveillance. (ISO 13485:2016.)

5 Usability engineering

Usability engineering, the same as human factors engineering applies knowledge about human behavior, abilities, limitations and characteristics in the designing process of medical devices, systems and tasks. The aim of usability engineering is to achieve adequate usability. Optimizing medical device usability improves safety, task accuracy, completeness and efficiency and user satisfaction. (IEC 62366-1:2015.)

5.1 Usability engineering process

Usability engineering process mitigates a risk caused by usability problems. Considerations of usability engineering are device users, device use environments and a device user interface. The problems are associated with correct use and use errors. To provide the safety of patients, users and others, establishing, documenting, implementing and maintaining the usability engineering process is needed. The process will address use interactions with the medical device according to the accompanying documentation. Transport, storage, installation, operation, maintenance, repair and disposal are included in the process. However, the process cannot be limited by these interactions. Personnel competent on the basis of appropriate education, training, skills or experience should pay a role while planning, carrying out and documenting usability engineering activities to a medical device. (IEC 62366-1:2015; FDA, 2016 p. 4.)

Depending on medical device and its applications, the users of the device can be professionals or non-professional users. However, the intended user of the device should be able to use the device without doing errors that can do harm to medical care, patient or user safety. The ability of the user to operate the medical device depends on the personal characteristics, which should be understood and evaluated in all intended user groups. Furthermore, the use environment can affect the usability of the device. The characteristics of all

intended use environments should be evaluated, understood and described for the purpose of usability engineering and evaluation. (FDA, 2016 p. 9.)

All points between the user and the medical device are noticed in a device user interface including all elements of the device which the user interacts with. A device user interface should take into account situations where sets up the device, uses the device or performs maintenance on the device. An efficient device user interface will advance correct use actions and prevent user errors that could lead to harm. User interface design includes any aspects to an extent to which the logic of information display and control actions is consistent with user expectations, abilities and likely behaviors at any point during use. Creating a device user interface is an efficient strategy during device design to reduce and eliminate user-related hazards. (FDA, 2016 p. 10.)

Usability engineering process is related to risk management process. The difference between these processes is that usability engineering activities consider and mitigate problems in user interaction without abnormal use, whereas risk management process considers abnormal use as reasonably foreseeable misuse. (Pitkänen & al., 2020 p. 67.)

5.2 Requirements of usability engineering process

Application of the usability engineering to medical devices standard IEC 62366 has two parts. Part one describes the usability engineering process whereas part two is for guidance to conduct the process. As the usability engineering aims to identify and minimize use-associated risks, the standard has information on how to notice the safety-related usability in analysis, development and evaluation of the device.

According to standard IEC 62366-1:2015 the usability engineering process should include preparation of user specification, identification of user interface characteristics related to safety and potential use errors, identification and description of hazard-related use scenarios, selection of use scenarios for summative evaluation, establishing user interface specification, establishing

user interface evaluation plan, designing user interface, performing formative evaluation and lastly summative evaluation. Some parts of the process may give some input to risk management process described in standard ISO 14971:2019. (IEC 62366-1:2015.)

The usability engineering process is usually made alongside developing a new product. User specification can be created from the information collected in user research, contextual inquiry, conceptual model and comparative analyses. To move forward in the process, functional analysis, task analysis or cognitive task analysis may be helpful methods to identify user interface characteristics related to safety. This information could be utilized in identifying known and foreseeable hazards and hazardous situations. As describing those situations, detailed specifications for use scenarios should be included in the created document. Also, in the process the use scenarios must be selected for summative evaluation. (IEC 62366-1:2015.)

Formative evaluation seeks to evaluate user interface design during the development rather than when the product is considered as a complete. Formative evaluation can be considered as a plan to develop, explore and evaluate user interface design. Summative evaluation is meant for confirmation the final user interface design. Both, formative and summative evaluation are considered as user interface evaluation activities. The user interface evaluation plan helps to synchronize user interface evaluation activities to other development activities. Evaluating the user interface is a responsibility of manufacturers that must be fulfilled during the development process and after the device is ready to be marketed. (IEC 62366-1:2015.)

Formative evaluation plan shall consist of methods used in evaluation, part of the user interface being studied and when in the usability engineering process to perform each of the user interface evaluations. Formative evaluation data can include usability tests and customer preference survey response. Most beneficial formative evaluations are designed in early state of medical device survey and development cycle, because it could give valuable information of user interface. (IEC 62366-1:2015.)

As mentioned, hazard-related use scenarios are selected for summative evaluation. Manufacturer can decide to choose all use scenarios or the subject of the hazard-related use scenarios based on severity of the potential harm that could be caused by use error. The purpose of summative evaluation is to confirm successful completion of the tasks associated with the hazard-related use scenarios. (IEC 62366-1:2015.)

6 Applying usability engineering to dry eye products and contact lens care solutions

The usability engineering process has already been completed for dry eye products and contact lens care solutions of Finnsusp. However, usability engineering file was not created during the development process, because the usability of the products was studied within clinical evaluations, risk managements and product validations. This was an acceptable method before MDR came into effect. The results of the evaluation of usability are included in the corresponding in each product's technical file. In this thesis the usability engineering process for dry eye products and contact lens care products is described at general level.

6.1 Products

Dry eye syndrome is a common ailment caused by insufficient tear secretion or excessive evaporation of tears. An adequate and consistent layer of tears on the surface of the eye is essential to maintain the health of the eye. The ailment cannot be cured; however, it can be alleviated. Dry eye syndrome can be caused by environment, aging or excessive use of digital equipment. (Heiting, 2022; Terveyskirjasto, 2021.)

Symptoms of the dry eye syndrome include itching, redness, dryness and watering of the eyes. Moreover, eye dryness can feel like something unknown is in the eye. To alleviate symptoms, moisturizing eye drops can be used as self-medication. (Heiting, 2022; Terveyskirjasto, 2021.)

Contact lenses are lenses placed directly on the surface of the eye. It is an alternative way to correct visual acuity rather than eyeglasses. The use of contact lenses is accompanied by an inflammatory risk, which is reduced by the right type of contact lens care products. (Terveyskylä, 2019.)

Contact lens care solutions can be divided into multipurpose contact lens solutions and hydrogen peroxide-based care products. Contact lens care solutions are designed to disinfect, clean, rinse and storage contact lenses while maintaining the safety and performance of a contact lens. (Heiting, 2022; ISO 18369-1, 2017.)

6.2 Use specification documentation process

The documentation process was planned by starting with dry eye products. IEC 62366-1:2015 was followed during the documentation process. Products with similar properties were investigated together as a group. The company's existing documentation was utilized for determine following user specification requirements. As a result for documentation process two use specification documents were created, one use specification for dry eye products and another for contact lens care products. Instead of usability engineering file, the documents are named user specifications as it evaluates the interface of user and the product and are created for already developed products.

The intended use for the dry eye products varies from alleviating the symptoms to treating and preventing the symptoms and signs of dry eye and moisturizing the skin around the eye. Contact lens care solutions are made for disinfecting, cleaning, rinsing and storage of contact lenses The intended uses for the products are listed in two tables based on the product line (Table 2 and 3).

Table 2 Intended use for dry eye products.

Product	Intended use
A and B	Moisturizing eye drops intended to relieve mild and moderate dry eye symptoms.
C and D	Intensive moisturizing eye drop intended to relieve moderate and severe dry eye symptoms.
E	Treating and preventing symptoms and signs of moderate and severe dry eye.
F and G	Treatment and prevention of signs and symptoms of moderate or severe dry eye and moisturizing. the skin around the eye and protecting them from cell damage.

Table 3 Intended uses for contact lens care products.

Product	Intended use
H	All-in-one type of contact lens care solution regimen for cleaning, protein and lipid removal, disinfecting, storing and rinsing all soft and silicone hydrogel contact lenses.
I	A multipurpose contact lens care solution regimen for cleaning, protein and lipid removal, disinfecting, storing and rinsing all soft and silicone hydrogel contact lenses.
J	A multipurpose rub-and-rinse care solution regimen for cleaning, disinfecting, storing, rinsing and moisturizing for especially silicone hydrogel contact lenses as well as all other contact lenses. In daily use removes impurities from the lenses
K	Intended for cleaning, disinfecting, neutralizing and storing of all contact lenses.

Intended use population for dry eye products are lay users with dry eye symptoms. The use population is not limited in age or general health condition. Products are suitable for sensitive eyes and contact lens users. Contact lens care solutions are intended for contact lens users. The intended part of the body interacting with the device is mentioned also in the use specification documents.

Intended use environment and user profile are requirements of the user specification. However, in this case, user profile is the same as intended use population. Some of medical device's interface is with patient and user, which should be noticed in use specification. As the eye drops are meant to be used multiple times a day, the use environment can be variable. Typical use

environment for contact lens care solutions is user’s home. However, variability is possible and being noticed during the use environment specification.

To finalize the user specification, operating principles of the devices are determined. Operating principles of the created documents includes the operating principle of packaging and formulation of the products.

The company has already identified of hazards and hazardous situations related to user safety as a part of the risk management process. The risk analysis for use specification file is made by applying the risk management file. In use specification, the use errors and associated factors possibly leading to the harm are identified, use scenarios are described and the severity of the harm is evaluated by utilizing a severity scale.

User interface specification includes testable technical requirements related to usability interface and if the user needs education for safe use. User interface can also examine the expected user needs. Based on the user needs, user interface requirements can be identified. In these products, formulations and packaging functions are studied. Accompanying documentation is considered as a part of the product, meaning that an instruction for use-leaflets has to be included in the user interface specification as part of the document. What comes to education needs, dry eye products do not require specific training of the end-user. However, use of contact education lens care products should always be trained for end-user by the optician.

Formative evaluation is a chapter which describes the studies to ensure the usability of the product. This part of the document focuses on properties of the product that would make the user experience pleasant. Such as proper, functionality of the packaging. Hazard-related use scenarios are taken into account in summative evaluation which includes usability testing in those parts where needed. The need of the usability test is described the in standard.

7 Conclusions

The aim of this thesis was to find and gather the utilized standards to confirm that the MDR's requirements are fulfilled. A further aim was creating use specification documents for dry eye products and contact lens care products with accurate definitions of user interactions and risks. The documents will be inspected and approved prior to deployment.

The products manufactured by Finnsusp are in a process of transition from the medical device directive to the MDR. Some of the documentation use which the specification documents are based on are under an updating process, which creates a risk that the use specification documents will soon be outdated. Used documents that are under update, are marked in the use specification documents. Marking the documents will speed up updating the documents.

To improve conformity, the usability engineering process should be included among the R&D processes. The benefits of following the IEC 62366 are not only to help fulfill the requirements of the MDR, but also giving guidance for investigating usability during development. As the formative evaluation is advisable performed during development, the possible test methods are presented in the standard. Effective formative evaluation can give valuable information about the usability and design of the product.

Implementation of the usability engineering process as a part of R&D processes, would be beneficial to create a base document for usability engineering, which could include the headings of the needed information and short descriptions of the contest of the chapter. By creating a base document, usability is studied in an early state of the R&D process. The base document could be linked to the project plan as an appendix to point out the methods on how usability is to be investigated. This type of working method would increase conformity and help to create of the concept for a new product.

During the thesis, it was observed that the needed information was both in physical documents and in electronic files. However, not knowing exactly where

the needed files are, the observation was made that the documents seemed hard to find. By updating the documentation policy, documents may become more usable. The aim of the update could be to ensure that the same policies are used by all employees, to simplify access to the needed documents and to clarify version control. These methods may save some time in searching, updating or accessing for the documents as a novice employee.

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