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Challenges of Medical Device Regulation for Small and Medium sized Enterprises

Abstract: For known reasons, the European Parliament was forced not only to revise the old Medical Device Directive (MDD) and the Active Implantable Medical Devices Directive (AIMDD), but to replace it with the extensive MDR. With the implementation of the Medical Device Regulation (MDR) in May 2017, manufacturers of medical devices will face new challenges for their products in the future, which also have to be implemented in a timely manner. Particularly small and medium-sized enterprises (SMEs) are concerned about whether a timely adaptation to the MDR and their requirements can be implemented. The conversion is associated with a huge effort for all producers of medical devices and certainly, produkt launchers. The purpose of this paper is to get an overview of the most relevant and emerging requirements that manufacturers need to adapt to sell their medical devices in compliance with the MDR regulations. It also explains the extent to which changes and innovations in the MDR are discusses and problems for SMEs.

Keywords: Approval of medical devices, Quality management

1 Introduction

Medical Device Regulation (MDR) – Patient safety first. When, in August 1994, the 93/42 EEC Medical Device Directive, published in July 1993, became national law, it created a European Union basis for quality and patient protection. Although the Directive has been steadily adjusted (the most extensive amendment to the MDD was made in 2007 with legal effect in 2010), the MDD framework remained outdated and unable to handle the large number of implants and software. In addition the silicon breast scandal in Europe led to questions concerning whether the MDD is sufficient to protect patients.[1] As a result, the European Parliament established a new comprehensive directive (MDR), which came into force in May 2017 [2].

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Because of the huge need of that law, the MDR became effective immediately, but with a transitional period of three years (Fig.1). The new regulation is considered to be a milestone for the product safety and product quality of medical devices. The MDR has given rise to comprehensive and detailed regulations that regulate almost all areas of medical devices. Manufacturing, placing on the market, and explicitly developing new classification modifications are at an unprecedented level. This MDR is only for the benefit of the patient. Only through extensive investments in the area of quality management companies can meet the requirements of MDR. The purpose of this paper is to provide an overview of the relevant challenges and implications of MDR implementation that medical device manufacturers, and especially small and medium-sized enterprises (SMEs), face.
2 Challenges of MDR

The MDR replaces the previous Medical Device Directive (MDD) 93/42/ECC and the Active Implantable Medical Devices (AIMDD) 90/385/ECC (Fig. 2). The new guidelines include 123 articles, so that they have significantly more complexity and impact, compared to the old laws. Some of the articles in MDR coincide in some point with those that existed before, but they have become much more detailed. In addition, new articles have been introduced which have never before been considered by public authorities. These new regulations are a major concern for medical device manufacturers, but especially small and medium-sized companies, as they are unlikely to be implemented much more easily. Because of the changeover, manufacturers will have to make considerable efforts. Following are some relevant and new requirements that will be mandatory for medical device manufacturers [2], [6].

2.1 Content requirements for the technical documentation

The technical documentation now replaces the older terminology of the "design dossier". An overview of the content of a technical documentation can be found in Annex II and III of the Medical Device Regulation. Due to the changes to the requirements of technical documentation, they must be completely revised. In addition, the technical documents must be kept safely for at least ten years and documentation of implantable products must be kept for at least 15 years [2].

2.2 Post Market Surveillance

Post Market Surveillance (PMS) is defined as "any activity that manufacturers carry out in cooperation with other economic operators in order to proactively collect and review experience gained with their products placed on the market or put into service on the market products are obtained, set up and kept up to date " [2]. Manufacturers have to demonstrate an active proof that the products are in the specified performance specification, as specified in the user manual. This monitoring depends on the risk class and the nature of the product and has to be an integral part of the quality management system. With the help of this post-market surveillance procedure, benefit-risk considerations can be analyzed. In addition, trends and messages can be determined. In case of problems with a product, which already got sold, the producer has to define appropriate measures and has to inform the competent authorities. If appropriate they have to inform the notified body. Manufacturers of products with risk class I need to prepare a post-market monitoring report. This report can be updated as needed. Manufacturers of class IIa, IIb and III products also have to produce a report after placing on the market and will be required to submit a safety report annually. Risk class I classifies low-risk products such as laser glasses, gauze bandages or clinical thermometers. Risk class IIa includes medium risk products such as ultrasound or hearing aids. Class IIb products are high risk products such as X-ray equipment or infusion pumps. Risk group III involves very high risk products such as implants or cardiac catheters. As a manufacturer of a class IIa product, they can keep the report up-to-date as needed, with updates at least every two years. The Safety Report of class III and implantable products has to be submitted to the notified body for reviewing. Thus, medical devices and documentation can be divided into three different groups.

2.3 Unique Device Identifier (UDI)

The unique device identifier (UDI) represents a current challenge for manufacturers in terms of the traceability of medical devices [3]. This system is an application for accurate product identification and recognition by giving an alphanumerical identification code/identifier. All manufacturers are obliged to comply with the requirements of UDI. The UDI contains a manufacturer-specific and product-specific UDI product recognition (UDI-DI), as well as a UDI production recognition (UDI-PI) and is used for reporting corrective actions and serious events. The purpose of this system is to enable a clear identification of each product on the market. The manufacturers are obliged to mark the UDI on the packaging of a product. This identification (code) should enable all products to be registered in a database (UDID). The manufacturer is obliged to indicate the UDI on every product and on all packaging levels. Also the used packaging dimension must be specified with length, height, width etc. In addition, it is required that the...
manufacturer introduce a list of all assigned UDI as part of the technical documentation [6].

### 2.4 Classifications

With the implementation of the new MDR, the number of classification rules has expanded from 18 to 22. Thus, all product classifications must be rechecked by the manufacture. The newly implemented classification rules can be found in Annex VIII of the MDR. A particular change is that some products will need to be classified by risk class III from 2020 onwards. Explicitly affected are products which find application in the heart or in the central circulatory system. Also, all active implantable devices, as well as their accessories and their control software, have to be classified as class III. Implantable spinal cord products have to be tested to class III, too. Special attention is given to the classification of software. In former guidelines software was never included. Now the MDR sets the minimum risk class for software to IIa up to maximum class III. A major effort for manufacturers is now that nanomaterials are considered. Thus secure and perfect functioning software is a must, especially when different medical data processing systems interact.

### 2.5 Scrutiny procedure

The scrutiny method is a response to negative experiences such as the "PIP scandal" in 2010 [5]. This procedure goes beyond the assessment and analysis of a notified body. Notified bodies are responsible for the laborious of conformity assessment procedures, which depends on the product’s risk class, and must undergo a scrutiny procedure. This process is initiated when it comes to class III implantable devices and class IIb products that have the potential to deliver drugs into the body. In a scrutiny procedure, the notified body checks the products for compliance and then creates a Clinical Evaluation Assessment Report (CEAR). This report will be forwarded via the European Commissions to a panel of experts who will decide on how to proceed on this product within 21 days. To ensure the safety of patients in the future, unannounced notified body examinations will take place. Thus, manufacturers must take care that their documents and processes are up-to-date. Thus an intense and fast interaction between manufactures, NBs and EC panels must be established, maintained and, of course, improved [4], [5].

### 3 Challenges for SMBs

In order to satisfy the MDR requirements, especially small and medium-sized medical technology companies face considerable difficulties. SMEs, relatively speaking, have to invest a great deal of effort in order to meet organizational and financial requirements of the new EU rules [7]. Producers of medical devices, especially SMEs, will have to re-adapt the products, documents and processes to ensure compliance with the changes and innovations in MDR. As described in the previous chapters, there are some completely new, but also several old, revised manufacturer requirements. Producers have to explicitly consider whether their product must have a new product classification or conformity assessment. The UDI also offers an extraordinary impact. If there is no UDI, manufacturers must implement a complete UDI system. In addition, post-market surveillance is relevant as it is necessary to check if there is a monitoring system or whether a new one needs to be developed. Due to the new requirements of the technical documentation, a considerable effort is also created here. To meet these requirements, many companies need to increase their quality management staff. It will take lots of time to review all specifications of all products to verify their conformity. An important factor is the power of SMEs, which is often improperly estimated, e.g. oversimated, by public authorities, which is expected to be not beneficial for SMEs. Another problem facing manufacturers of class IIa, IIb and III products is that it is not yet clear when the first notified body will be accredited according to the MDR. The notified body will have to spend much more effort, as they will have to work with a panel after the new MDR and have to apply the quality so that they can certify companies. Thus, this situation represents another hurdle for small and medium-sized companies, because only the big companies are certified first. If a medical product companies does not have a suitable notified body, it does not have many options. Either the company will be closed, sold, or the company specializes in other things.

### 4 Implementation of MDR at CRS medical GmbH

CRS medical GmbH, Aßlar, Germany is an SME who mainly produces and distributes products of risk class I. The implementation of MDR poses several challenges for the company CRS medical GmbH: The company has to implement the very high demands of MDR within the given time. In addition, the new requirements must be transferred to the products already placed on the market. To ensure a successful transition
to MDR, a congress (March 2017) was visited, addressing the major changes. Since early 2018, the staff has been expanded, which supports the company in the implementation of MDR. The products’ classification has to be checked as well to see if the classification will change. The next step will be the comparison and adaptation of the MDR requirements to the technical documentation with the current technical documentation. The implementation of the UDI and the introduction of UDI processes is also targeted. Other seminars and training sessions will be attended to meet the implementation of the MDR requirements. The application of the new MDR will be reflected in the quality assurance QA system by adapting Standard Operation Procedures (SOPs), Work Instructions (WI) and Forms.

5 Discussion and Conclusions

Implementing MDR has dramatically increased the number of challenges and requirements for every medical device producer. Comprehensive and detailed regulations have entered into force with MDR, which regulates almost all areas of medical devices. Manufacturing, marketing and new classification modes are at unprecedented levels. This serves the well-being of the patient, but is associated with a lot of effort to meet all requirements and innovations in the conversion of the MDD and AIMDD to the new MDR. Manufacturers are required to comply with all these requirements to sell their products on the European market. The content of MDR has increased dramatically compared to older guidelines and has been revisited and explained in more detail than ever before. Attention is paid to the new requirements: the introduction of UDI or the new requirements for technical documentation. Also, the risk classification of software is a relevant point, which was not previously given. The aspects described in this paper are some of the new adjustments that need to be met to be compliant. For all producers, the adjustments mean a great deal of organizational and time expenditure. Due to the composition of medical device companies in terms of size, SMEs are particularly challenged. There are a lot of small companies with about ten employees and little big companies [8]. Specialy these companies have to manage intense MDR induced resource and financing problems. Also, new qualified personnel must be hired to meet the future demands. The resulting financing problem will lead to more expensive products on the market. As a result, the portfolio of medical devices is expected to be reduced dramatically. As the transitional period is only three years, manufacturers, and especially SMEs, should promptly begin to address the new MDR. Whereby it can be too late now, because it will be difficult for small companies to implement all requirements in time. Finally, there is a big issue left open: in remains to show that the MDR serve the patients not only with respect to quality and protection, as expected, but also with latest biomedical devices [6].

Acknowledgement: The authors would like to thank CRS medical GmbH for cooperation, support and helpful discussions.

Author Statement

Research funding: The author state no funding involved. Conflict of interest: Authors state no conflict of interest. Informed comment and ethical approval was not required since no individuals were included in this study.

References