Quality Task Group Information

Implications of MDR for the economic operator

List of authors: B. Amann, T. Appel, D. Diedrich, A. Forster, K. Gehrmann, C. Graßhoff, A. Hartwig, A. Jones, G. Kirmse, S. Krüger, J. Metzing, A. Papadopoulos A. van Waveren, U. Zimmermann

Introduction

The Medical Device Regulation (MDR [5]) has been in force since 25 May 2017 and the specified transition period is soon coming to an end. For the economic operator there is the question of how the legal regulations are applied.

In principle, **MDR REGULATES THE MANUFACTURE AND PLACEMENT** on the market of medical devices for the entire EU without having to first be transposed into national law (as was the case for the Medical Device Act [MPG)] [2].

THE MDR REGULATES THE MANUFACTURE and placement on the market of medical devices for the entire EU.

Whereas directives are transposed into national law, EU regulations become immediately enforceable as law. In Germany, for example, the EU Medical Device Amendment Act (MPAnpG-EU) transposes to German law the provisions of EU regulations that are valid throughout Europe [3].

However, there are certain issues that are regulated at national level. In the case of Germany, these are as follows:

- The Medical Device Implementation Act (MDG) and transferred regulations: are still under preparation
- Medical Device Operator Regulation: the currently valid version from 29 November 2018 remains unchanged

Changes introduced by MDR for economic operators

- The medical device identification system (MDR Article 2(15)) changes with the incorporation of a Unique Device Identifier [UDI])
- Additional documentation obligations may apply because of the new cla ss III devices.

Changes introduced by MDR for manufacturers

- Classification system
- More stringent requirements for collection of clinical data
- More stringent requirements for certification
- Traceability of implants over their entire life cycle
- EUDAMED database
- Unique device identification system

With the **EUROPEAN DATABASE** for medical devices (EUDAMED Database) there will be greater device transparency. The database follows a resolution of the EU Commission (2010/227/EU) in which the EU states the purpose of EUDAMED as follows:

THE EUDAMED DATABASE will lead to greater device transparency.

The European Medical Device Database aims to improve market surveillance by giving competent authorities quick access to information about manufacturers and their authorized representatives, products and certificates, and vigilance data; it is also intended to contribute to the exchange of information on clinical trial data and to the uniform application of the above-mentioned guidelines, in particular with regard to reporting requirements.

All changes are aimed at increasing patient safety and, at the same time, at harmonization of medical device regulations.

The MDR timeframe is complex (here only the most important aspects):

- 26 May 2020 is considered a critical deadline since it marks the end of the transition period for placement on the market of class I devices in accordance with MPG.

- The committee for environmental issues, public health and food safety of the European Parliament decided to extend that transition period on 3 December 2019 by means of a corrigendum to the European Medical Device Regulation. (https://www.aerzteblatt.de/nachrichten/108309/EU-Parlament-verlaengert-Uebergangsfristen-fuer-Medizinprodukte-niedriger-Risikoklassen)
- Class II and III devices can still be placed on the market until 26 May 2024 provided they have a valid certificate as per MPG (if no major changes are made to them).
- The manufacturers should register their UDI data (codes) for class III devices by 25 May 2021 with EUDAMED (class I by 2025), but delays are possible
- The UDI codes should be affixed to reusable class I devices as from 25 May 2027.

Implications of changes to the classification system

Class I devices for which a conformity declaration was issued pursuant to Directive 93/42/EEC before 26 May 2020 and for which, pursuant to MDR a notified body must be involved, may still be placed on the market and operated provided that no major changes have been made to their design or intended purpose.

AS SOON AS CHANGES are made to the class and, accordingly, the conformity assessment procedure, the manufacturer must overcome specific challenges.

CHANGES TO THE CLASSIFICATION system: As soon as changes are made to the class and, accordingly, the conformity assessment procedure, the manufacturer must overcome specific challenges. Several changes are made to the device classification system. In addition to the introduction of the new class Ir for reusable surgical instruments, the requirements for implantable class IIb devices, in particular, have been tightened. Furthermore, numerous device categories have been assigned to a higher risk class.

In addition to tighter requirements for the manufacturer, the notified bodies, too, are now forthwith subject to more stringent regulations. Various additional requirements must now be fulfilled to approve medical devices. There is no need for the involvement of the notified bodies in the conformity assessment procedure for class I medical devices. Besides, MDR does not require certification of the quality management system by a notified body for class I medical devices. An exception to that rule is class Is, Ir and Im medical devices:

- Is: Devices placed on the market in a sterile condition
- Ir: Reusable surgical instruments(r denotes “reusable”)
- Im: Devices with a measuring function

For these “class I*devices” the manufacturer must involve the notified bodies in the conformity assessment.

Hitherto class I devices now assigned to a higher class (class Ir, material medical devices, software) as well as all class I devices must meet the provisions of MDR. To date, few notified bodies have been accredited for MDR, something that can result in a bottleneck situation since all existing devices assigned to a higher class will have to be newly approved.

MDR requires manufacturers to greatly extend the scope of testing and documentation, including for example:

- More devices come within the remit of the medical device regulations (e.g. software)
- The essential requirements are extended (biocompatibility, etc.)
  - More extensive burden of proof
  - Mandatory clinical tests for class III devices
  - Some devices are assigned to a higher class (MDR risk class)
- Documentation on medical device, market surveillance
  - Periodic safety reports must be compiled
- Information on the medical device service life (end of life)
- Detailed requirements for the instructions for use
- The original equipment manufacturer (OEM [4]) business (supply of devices from a different manufacturer under one’s own name) will be more stringently regulated

- The manufacturer's monitoring and liability obligations will be extended
- The procedures of the various notified bodies are to be harmonized to a greater extent
- Monitoring of manufacturers will be intensified

For devices belonging to the new **CLASS IR** (primarily reusable surgical instruments) the manufacturer now requires a certificate with details of reprocessing from a notified body. The devices will then no longer feature the "CE" but rather the CE marking and the identification number of the notified body (e.g. CE[0123])

FOR DEVICES BELONGING TO THE CLASS IR the manufacturer requires a certificate with details of reprocessing from a notified body.

But devices already in the possession of the economic operator may continue to be used without restriction.

In general, MDR regulates the obligations of manufacturers and contains little information on those of the economic operator. Those mentioned include:

- Registration of custom-made class III devices (MDR, Article 27(8))
- Stricter regulation of custom-made manufacture. These include, among other things, a combination of medical devices not provided for by the manufacturer or the use of a medical device contrary to its intended purpose. Custom-made manufacture is only possible if no equivalent device is available on the market for the specific requirements.
- Reprocessing of single-use devices can be regulated at national level

The more stringent burden of proof and documentation requirements will have implications for the content of the instructions for use. The instructions for use must be expressed and explained in more precise terms. That includes:

- A more succinct and precise description of the intended purpose
- A more detailed description of validated reprocessing processes
- Limitations of the device service life (reprocessing cycles)

In Germany, the Medical Device Adjustment Act (MPAnpG-EU)/ Medical Device Implementation Act (MDG) shall apply for country-specific regulations but these are currently available only in draft form. They regulate (among other things):

- Incident reporting and monitoring requirements (largely unchanged, includes the regulations from the previous Medical Device Safety Regulation (MPSV))
- Hospitals that reprocess "single-use devices" (here: devices not declared for reprocessing by the manufacturer) must be registered
- Clinical trial regulations
- Regulations on penalties and fines

It is often mistakenly thought that MDR regulates **TRACEABILITY**. But in terms of MDR that only applies to the medical device manufacturer. For the economic operator traceability of medical devices is described in Annex 2 of the Medical Device Operator Regulation (MPBV) and no changes have been made to date.

THERE ARE NO CHANGES regarding traceability of medical devices for the economic operator.

Summary

With the resolution of 25 May 2017, the new MDR will come into force at the end of May 2020. That applies to class I medical devices. This introduces many changes regarding the documentation and verification obligations for the manufacturer of these devices. There continue to be some uncertainties as regards interpretation of MDR as well as of the associated national regulations.

ONE RISK FACED BY THE ECONOMIC OPERATOR is assurance of the availability of medical devices because not all class I devices will conform to MDR by the deadline of 25 May 2020. In such cases, it is recommended to contact the manufacturer of these medical devices and enquire beforehand about their availability.

ONE RISK FOR THE OPERATOR is assurance of medical device availability.

Another change for the economic operator relates to the instructions for use. Due to the additional requirements addressed to the manufacturer, the instructions for use will be formulated in more precise and detailed terms but may also impose limitations on the user.

THE ROLE OF THE KRINKO/BFARM Recommendation* remains unchanged.

A new Medical Device Operator Regulation is expected but to date no draft of that is available. The role of the **KRINKO/BFARM RECOMMENDATION*** remains unchanged.

KRINKO/Farm Recommendation: Hygiene requirements for processing medical devices, jointly compiled by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (KRINKO) and the Federal Institute for Drugs and Medical Devices (Farm)

References

[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EG) 178/2002 and Regulation (EG) 1223/2009 and repealing Council Directives 90/385/EWG and 93/42/EWG

[2] Dr. Christoph Götschkes, Medizinprodukterecht für Betreiber, Zentralsterilisation 2019; 27 (2): 84–92. (in German only)

[3] Lecture by Dr. Jäkel, DGSV-Kongress 2019

[4] OEM – Original Equipment Manufacturer

Information for Authors

Zentralsterilisation – Central Service is a professional journal for all aspects of sterile supply. It contains original articles, reviews, recommendations, guidelines, reports from the field as well as short communications and letters.

Manuscripts already published or submitted for publication elsewhere cannot be considered for publication. All manuscripts are subject to peer review. Evaluation criteria differ depending on the manuscript category (e. g. reports from the field, original articles). Upon acceptance for publication, copyright of the article is transferred to mhp Verlag GmbH. The designated principal author will receive proofs for final approval.

The preparation of scientific papers should essentially be in accordance with the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (Ann Intern Med 1997; 126: 36-47). The language of the journal is German and English. Manuscripts in one of theses languages should be sent directly to the Production Editor and submitted in an electronic format (disc or E-mail: zentrsteril@mhp-verlag.de). Figures have to be sent in separate files (high resolution JPG, TIFF or PDF).

Articles should include a title page with the names, academic degrees and addresses of all authors, Summary, and Keywords. The text of scientific articles should be composed of Introduction, Material and Methods, Results, Discussion, Acknowledgments (if applicable) and References. Articles other than scientific papers may have a different outline, but should always contain a summary. All figures and tables must be mentioned in the text and be supplied with a short caption.

References must be listed in the numerical order of their appearance in the text (not alphabetically!). Use the following format for references:

- Reponen T, Wang Z, Willeke K, Grinshpun A: Survival of Mycobacteria on N95 Personal Respirators. Infect Control Hosp Epidemiol 1999; 20(4): 237-241.
- Eisen HN: Immunology: An introduction to molecular and cellular principles of the immune response. 5th ed. New York: Harper and Row, 1974: 406ff
- Weinstein L, Swartz MN: Pathogenic properties of invading microorganisms. In: Sodeman WA Jr, Sodeman WA, eds. Pathologic physiology: Mechanisms of disease. Philadelphia: WB Saunders, 1974: 457-472.

For further information please contact the editorial staff: E-mail: zentrsteril@mhp-verlag.de