

Life Sciences

Newsletter

Keeping your business healthy
Update on Medical Devices



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EU Medical Devices Regulation to come in May 2020

Background

A medical device is an instrument, device, equipment or software intended by its manufacturer to be used in humans for such purposes as diagnosis, prevention, monitoring, treatment, alleviation of disease or injury. Medical devices are particularly regulated health products. To be put on the EU market, a medical device must obtain a CE marking, which requires the conduct of a conformity procedure on the medical device in question.

The conformity procedure a medical device has to undergo in the EU shall demonstrate it meets legal requirements to ensure its safety and intended performance. EU Member States can designate accredited Notified Bodies to conduct conformity assessments. The conformity assessment by a Notified Body usually, depending on the type and class of the medical device, involves an audit of the manufacturer's quality management system and the review of the technical documentation prepared and provided by the manufacturer on the safety and performance of the device.

The legislation of the EU Member States regulating medical devices currently are EU Directives (Directive 93/42/EEC on medical devices, Directive 98/79/EC and Directive 90/385/EEC), which soon will be replaced by the EU Regulation 2017/745 on Medical Devices (MDR). The MDR changes the European legal framework for medical devices, it broadens the scope of the products and operators covered under this legislation and provides for increased responsibilities and obligations for both, manufacturers as well as the Notified Bodies. The MDR entered into force May 2017 and has a staggered transitional period of three years. It will fully apply from 26 May 2020 on. During the transition period, manufacturers can place devices on the market under the currently applicable EU Directives (93/42/EEC, 98/79/EC and 90/385/EEC) or under the new Regulation if they fully comply with these.

Implementation of the MDR – status quo in Germany

The implementation of the MDR, so far, does not proceed as expected. There are several problems accompanying the implementation process.

The MDR request for a general new registration of all Notified Bodies which are responsible for certifying medical device companies and their products. There are however significant bottlenecks in this regard to overcome: so far, only 21 out of 59 European Notified Bodies have applied for a new appointment as certified Notified Body upon the MDR becoming applicable. Of these, five are based in the UK,

whose future as EU Member State is unknown due to the Brexit proceedings. The European Commission estimates that no more than 12 Notified Bodies will be appointed by the end of 2019, five months before the MDR deadline. With tens of thousands of medical devices undergoing the certification process and the Notified Bodies requiring three to nine months to certify a product or even longer due to increased demands, capacity issues are expected. It most probably cannot be guaranteed that Notified Bodies will have enough capacity to ensure the continued authorization of products by May 2020. This applies all the more as numerous new product categories will require certification for the first time due to new classification criteria under the MDR. In addition to this capacity lack with the Notified Bodies, the Eudamed database as well as important national regulations are still not in place.

The German Medical Devices and Med Tech Association (BVMed, Bundesverband Medizintechnologie) as well as other players in the medical device sector see a threat in particular to small and medium-sized companies, which need - due to the high costs - financial support and incentives (eg for the acquisition of sites, physicians and patients for participation in clinical trials for obtaining results as basis for the clinical data required under the MDR). In particular, the development of orphan medical devices with small case numbers are seen to require governmental support programs and special regulatory regimes to ensure high-quality patient care. Otherwise, there would be a threat of slowing down product development and deterring potential founders. In order to ensure access to medical devices required for patient care, immediate and coordinated action by EU Member States, the European Commission and the European Parliament would be necessary according to the BVMed. Also, a more open and transparent communication by the European Commission on the topics registration of Notified Bodies, functionality of Eudamed and process with Expert Panels is highly desired by the industry in order to enable the medical device companies to prepare best for the upcoming changes.



One year to go: questions and answers on the MDR

What are the key changes of the MDR?

Current requirements under the applicable medical device regime remain. In addition, the MDR imposes further requirements or stricter standards and broadens the scope of products covered (eg internet sales of medical devices and medical devices used for diagnostic and therapeutic services offered at distance now are covered by the Regulation).

Compared to the currently applicable Directives the MDR re-classifies certain types of medical devices (eg standalone software or software-containing products) due to stricter classification rules. For some already “authorized” products the new regime thus brings the requirement for a second conduct of the conformity procedure due to new classification criteria. The possibilities of how to conduct the conformity procedure also experience some changes. The MDR further brings changes to OEM-PLM-structures.

Under the new legal regime stricter and longer archiving and documentation requirements are imposed on the manufacturers. The implementation of a post-market surveillance system is mandatory, as are reporting obligations to the data base Eudamed, the implementation of systems for applying the so-called unique device identification (UDI) and the obligation of having a compliance officer in place.

Overall, the MDR brings higher efforts regarding documentation and costs due to the stricter regime.

What stricter standards imposes the MDR on manufacturers?

- higher standards on the **technical documentation**. The product-related descriptions for eg the intended use and structure of the product for are to be provided in more detail than under the Directive as well as on the clinical data.
- a **quality management system** shall be imposed by the manufacturer for certain medical devices. The quality management system shall set up a strategy for regulatory compliance, identification of applicable general safety and performance requirements, handling communication with competent authorities, Notified Bodies and other economic operators.
- the manufacturer has to implement a **post-market surveillance system** with stricter reporting obligations.

- according to the MDR, every product in future is required to obtain a unique device identification (UDI). Therefore, a **unique device identification system** is to be implemented to enhance the traceability and the effectiveness of post-market safety-related activities. For standalone software medical devices more specific regulations apply for changes in the product such as in the algorithm, the data base structure and others.
- a **person** qualified in, and in charge of, ensuring **compliance** with applicable regulations, will continuously liaise with authorities, and notably record and notify certain events occurring with respect to a marketed device.
- the MDR also intends increased transparency, with information on medical devices and studies being made public; therefore the **European Database for Medical Devices (Eudamed)** is extended and made accessible, at least partly, to not only governmental institutions, but also to manufacturers, Notified Bodies and the public.
- **archiving periods** for documents such as the technical documentation and conformity declaration are increased from five to ten years (for non-implants) from the last product covered by the conformity declaration being placed on the market. This also applies to EU-importers. Please note that according to ISO 13485 the archiving period shall at least last for the life cycle of the product, which is specifically important for products with a life cycle of 10 years and more.

What changes brings the MDR for OEM-PLM-structures?

With OEM-PLM-structures mostly the PLM (Private Label Manufacturer) is the one responsible for market “authorization” and post-market surveillance of the product. Thus, only the PLM is disclosed on the product’s labelling as manufacturer. At the same time, with OEM-PLM-structures, currently the PLM in most cases has no access to the technical documentation of the product due to restrictions imposed by the OEM (Original Equipment Manufacturer) or for other reasons. The MDR however requires the PLM to have full access to the technical documentation. Thus, the current OEM-PLM-structures will not be able to endure under the MDR if the structures and agreements between PLM and OEM are not adapted respectively. Some Notified Bodies already require full access to OEM technical documentation when auditing a PLM.

What are the changes for Notified Bodies due to MDR?

The MDR puts more emphasis on the product life-cycle approach to safety, which is supposed to be backed up by respective clinical data to be provided by the manufacturer and assessed by the Notified Bodies in the course of the conformity procedure.

The MDR thus implements stringent requirements for the designation of Notified Bodies, with increases control and monitoring by the national competent authorities and the European Commission. In future, the surveillance of manufacturers by Notified Bodies is more rigorous to reduce risks from unsafe medical devices. A more stringent documentation is required of the Notified Bodies. Also, a so-called Scrutiny Procedure is implemented by the MDR. Notified Bodies may be required to report any new application for conformity assessment for a high-risk product to an expert panel (the Medical Device Coordination Group, MDCG).



What steps manufacturers need to undergo to ensure compliance with MDR?

- check the product portfolios to find out whether more of the devices fall within the scope of the MDR compared to the Directive
- identify whether the medical device(s) have been classified correctly against the new risk classification criteria under the MDR
- ensure that medical device(s), in particular labelling, technical documentation and quality management system, comply with MDR requirements as well as with the common specifications for particular groups of products, and with general safety and performance requirements
- ensure that increased requirements for clinical evidence are met
- consult responsible Notified Body to evaluate potential compliance issues and develop a plan to address them
- if required, pass a conformity assessment carried out by a Notified Body
- assign a basic unique device identifier (UDI) and provide it to the UDI database
- ensure that a person responsible for regulatory compliance is in place
- submit key information about the manufacturer, and authorised representative (and importer if the manufacturer is based outside the EU) to the electronic system Eudamed
- ensure that sufficient financial coverage is in place in respect of a manufacturer's potential liability
- meet the post-market surveillance and vigilance requirements, such as conducting field safety corrective actions and reporting serious incidents to the competent authority
- ensure internal processes are in place to meet new vigilance reporting timescales

By when do medical device manufacturers need to comply with the MDR?

Manufacturers of formerly certified medical devices had the opportunity of a transition period of three years, currently one year left, to meet the requirements of the MDR by 26 May 2020. For certain devices this transition period can be extended until 26 May 2024, however, specific requirements must be met to be granted such extension.

Are there any “grandfathering” provisions for currently certified medical devices?

No. There are no “grandfathering” provisions. All currently certified medical devices and active implantable medical devices must be re-certified in accordance with the new requirements latest by 26 May 2020 (unless an extension was granted).

What is the “sell-off” provision about?

The “sell-off” provision is intended to limit the time during which medical devices that are compliant with the Directives and have already been placed on the market may be made available. Any medical devices that are still within the supply chain and that have not reached their final user (eg a hospital) on 27 May 2025 are no longer marketable and must be withdrawn from the supply chain. Once a Directives-compliant device has been made available to a final user by this deadline, the further provision of this device is not subject to the MDR.

What are the consequences for non-compliance with the MDR?

In case of non-compliance with the MDR-requirements with respect to a product upon expiry of the transition period, as applicable, an authority or Notified Body may limit or withdraw the CE mark of such product, each if appropriate based on its assessment of the specific case, and/or prevent the medical device from being marketed. Worst case, the manufacturer will not be able to market its device in the EU any more or at least for a specific period of time, although the product has been marketed before under the Directives.

In addition, the EU Member States are obliged to lay down rules on penalties applicable for infringement of the provisions of the MDR and to take all measures necessary to ensure that such are implemented.



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Medical devices and Brexit

Ongoing Brexit proceedings

Following the outcome of the EU referendum, the Medicines and Healthcare products Regulatory Agency ("MHRA"), is working closely with the UK Government to evaluate the best options and opportunities available for the safe and effective regulation of medicines and medical devices in the UK.

While these negotiations continue, the UK remains a full and active member of the EU and consequently all the rights and obligations of EU membership remain firmly in place.

Implementation of the MDR – status quo in UK

As currently drafted, the UK Government's EU (Withdrawal) Bill, only convert EU laws that are currently operative in the United Kingdom into UK law when/if the UK exits the EU. In this regard, the MDR will still be in "transition" on 31 October 2019 and will not be automatically implemented into UK law.

The MHRA has stated that it is continuing its preparation to implement the MDR and that irrespective of the outcomes of Brexit, it wishes to maintain a close working relationship with the EU regarding medicines and devices regulation.

As such, it is likely that the UK Government will pursue domestic legislation that aligns closely with the MDR and current regulatory framework. Currently, we thus suggest closely monitoring communications from the MHRA, as the political landscape continuously evolves.



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The MDR from a Spanish perspective

Background

Medical Devices are regulated by the national competent authority, the Spanish Agency of Medicines and Medical Devices (AEMPS), which acts as a Notified Body for CE marking and guarantees quality, safety, efficacy and accurate information on medicines and medical devices marketed in Spain, as provided by Royal Decree 1591/2009, of October 16, on medical devices.

Implementation of the MDR – status quo in Spain

Although we are still in the transition period, Spanish companies are working against the clock to prepare a detailed programme to implement the novelties and avoid the withdrawal of their medical devices from the market if they do not comply with the new requirements. It is essential to guarantee that the industry can keep providing solutions to the patients and healthcare systems. In order to facilitate the implementation, the AEMPS has published on its website the European Commission's Guide titled "Implementation Model for Medical Devices Regulation. Step by Step Guide".

In addition, the Spanish Federation of Health Technology Companies (FENIN), which represents, coordinates and defends the interests of the Spanish companies on medical devices before the regional, national and European authorities, has recently requested that the Spanish Ministry of Health authorize the necessary human and financial resources to strengthen the department of medical devices of the AEMPS, in order to adapt it to the new EU regulatory requirements.

A year away from the fully enforcement of the MDR, it is still too early to have a complete picture of the new medical devices market and the effectiveness of the post market safety related activities. Spanish authorities still need to work on penalties applicable for infringement of the provisions of the MDR in order to ensure its complete implementation.



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Overview on medical devices in Russia and the EAEU

Background

Eurasian economic integration of the Eurasian Economic Union (EAEU), comprising Armenia, Belarus, Kazakhstan, Kyrgyzstan and Russia, provides for the medical devices market to be common within the EAEU. This makes the regulatory and legal field for the circulation of medical devices similar to what is found in the EU. Medical devices are regulated both, at EAEU level and at the national level by EAEU member-states. The Eurasian Economic Commission (EEC), much as its European counterpart, adopts high-level regulations and provides general guidance, while national authorities regulate the circulation of medical devices within national borders. In Russia, the Federal Service on Surveillance in Healthcare (RZN) is responsible for registration and monitoring, as well as controls over safety and quality, and post-market surveillance of medical devices.

Recent development

Registration duality

The EEC adopted registration rules and requirements regarding the circulation of medical devices within the EAEU in early 2016 (Decision of the Council of the EEC No. 46 of 12 February 2016). The rules and procedures are largely based on national requirements, but are more detailed and stringent. Harmonizing the rules takes time and therefore a transition period is set until the end of 2021.

During this time, manufacturers of medical devices may choose either to use national registration procedures or to opt for the regulations passed by the EAEU. The first applications under the EAEU procedure were filed only end of 2018.

Implementing and enforcing the new rules on the scale of the EAEU is a gradual and challenging process, and Kazakhstan has already proposed to extend the transition period up until the end of 2025. The EEC may consider this proposal if the harmonization should not have advanced satisfactorily by 2021.

QMS (Quality Management System)

Similar to the MDR, regulations by the EAEU impose an obligation on manufacturers of medical devices to maintain a quality management system (Decision of the Council of the EEC No. 106 of 10 November 2017). This system amounts to a set of requirements and procedures that are based on international standards (eg ISO 13485) among others. The system is to be implemented and adhered to by manufacturers depending on the class of the medical device that they produce, which reflects a risk-based approach to quality management.

The transitional period for QMS requirements has expired in March 2019. Manufacturers of medical devices distributed within the EAEU may now be subject to QMS audits. In April 2019 the EEC has published and adopted a draft decision on qualification requirements applying to inspecting organizations that may conduct the audits. The RZN has declared that organizing and ensuring these inspections under the EAEU requirements is one of the goals of the Russian authority for 2019.



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With our global reach, we are also able to provide a range of other services to our life sciences clients such as consulting, legal operations and technological solutions, supply of interim legal professionals and support for high/low volume risk business as usual work.

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