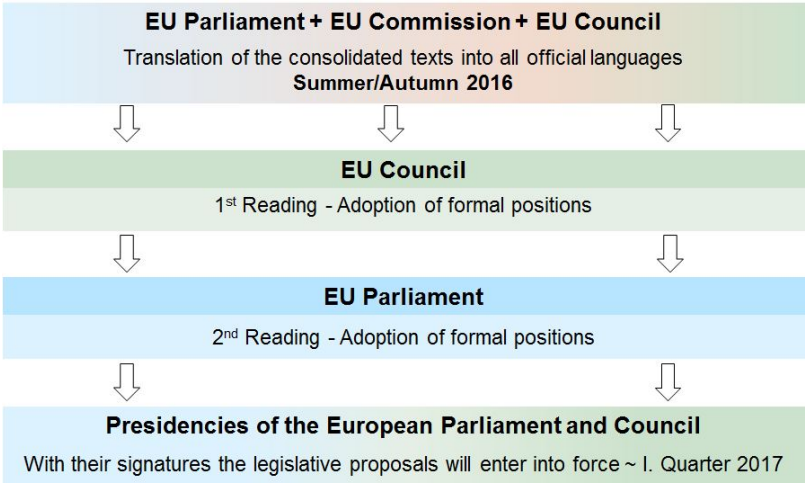
European Medical Devices Regulation (MDR) and
In-Vitro Diagnostic Medical Devices Regulation (IVDR)

In the course of the Trilogue negotiations, the European institutions Commission, Parliament and Council agreed on a compromise regarding the proposed regulatory framework for medical devices and in-vitro diagnostics. The consolidated texts of the MDR and IVDR were published for the first time on June 27, 2016. Please find the latest drafts of MDR and IVDR in the German as well as in the English version on our website.
Additional information can be found on the website of the European Commission: Revisions of Medical Device Regulations.



The European Commission`s Legal Service will review and revise the texts for MDR and IVDR only with regard to formal mistakes – the so called „technical Inconsistencies“. According to the EU commission, the content of the texts should remain untouched.

General Comments

The proposals of the MDR and IVDR are much more comprehensive and detailed compared to the former Directives. Nevertheless, many articles and annexes still have to be amended respectively specified; e.g. criteria for the designation of notified bodies, technical requirements for the reprocessing of single-use medical devices or the use of nanomaterial in the development and manufacturing of medical devices. By means of implementing and delegating acts the European Commission needs to address the still missing aspects of the regulations.

European Database – Eudamed and UDI

One key element of the MDR and IVDR is the introduction of a European database in order to increase transparency, ensure traceability of medical devices and to facilitate the flow of communication between manufacturers and operators of medical devices, notified bodies, member states and the European Commission. In Eudamed, different information/data bases will be integrated; e.g. data bases for the registration of the products with a Unique Device Identification Number (UDI) as well as for economic operators, notified bodies and data bases for collecting information about conformity assessment procedures, certificates, incidents and clinical studies.

Notified Bodies

According to the institutions of the European Union the perfect functioning of notified bodies is crucial for a high level of quality and safety for medical devices and in-vitro diagnostics. The procedure for designation and monitoring of notified bodies was therefore regulated more extensively and sharpened. Notified bodies are obligated to employ medical doctors or clinical experts and to implement a rotation system for lead auditors in surveillance audits.

Unannounced Audits

The right and duty of notified bodies to carry out unannounced audits at least once in five years shall verify that medical devices are manufactured in continuous compliance to the regulatory requirements and the manufacturer's quality management system. Within the context of the unannounced audit the notified body tests an adequate sample from the production in order to verify that the sample is in conformity with the technical documentation.

(New) Challenges for Manufacturer, Suppliers, Importers, Distributors and Authorized Representatives in Europe

Manufacturers in the EU do have to fulfil extensive obligations since quite a long time. These obligations are now described in the two Regulations in more detail and also cover the whole supply chain of the medical devices.

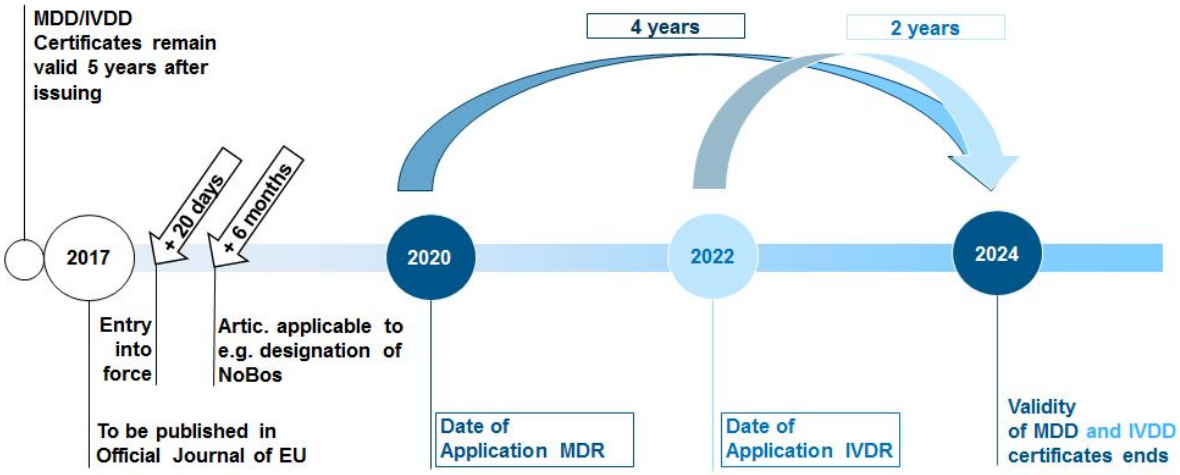
The risk management system, the vigilance system and the post market surveillance system are more clearly postulated as integral parts of the quality management. The gathered data out of these systems have to be systematically analysed and documented in continuous reports by the manufacturer and are especially used for updating the technical documentation.

Individuals responsible for the conduct of clinical evaluations have to provide evidence for their high clinical competence.

Manufacturers need to employ a person who is responsible for regulatory compliance.

Furthermore, manufacturers have to conclude a liability insurance agreement in order to financially cover damages caused by faulty products.

Do you know the revised transition period terms of MDR/IVDR?



Did you know there is a double safety mechanism for high risk products?

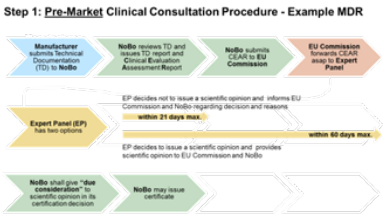
The basic principle for performing a conformity assessment procedure remains the same. However, the following products

MDR: Implantable class III products as well as active class IIb products which are intended to administer and/or remove medicinal products from the body, *IVDR:* Class D products, unless common specifications are available and if this kind of product will be certified for the very first time,

are subject to a **double safety mechanism** consisting of:

(1) Clinical consultation during the pre-market assessment;

(2) Scrutiny mechanism of conformity assessments (post-market).



Did you know that certain products with only an aesthetic or another non-medical purpose are now covered by the MDR?

This enlarges the regulation's scope of application. However, aesthetic or other non-medical products will only be covered by the new MDR if they are similar to medical devices in terms of functioning and risk profile. A list of these products can be found in Annex XV of the MDR, e.g. coloured contact lenses or equipment intended to be used to reduce, remove or destroy adipose tissue.

Did you know that the classification of IVDs will fundamentally change?

Whereas the classification of medical devices into four classes will remain the same, the list-based classification of IVDs was transferred into a rule-based system.

This new system is based on the GHTF scheme, which divides IVDs also into four classes depending on the particular risk for the individual and the society.

Class	Risk	Examples
A	Low individual risk and low risk to public health	Analyser for clinical chemistry, sample containers
B	Moderate individual risk and/or low risk to public health	Vitamin B12, pregnancy self-tests, urine test strips
C	High individual risk and/or medium risk for public health	Blood glucose self-tests, HLA typing, PSA tests, Rubella, cancer diagnostics, CDx
D	High individual risk and high risk for public health	Blood donor screening (HIV/HCV), blood grouping (A,B,O)

Do you know the new provisions for the re-use of medical products?

Member states can permit or ban reprocessing of single-use products at national level. According to the new MDR a “reprocessor“ should be considered the legal manufacturer of the reprocessed device and therefore needs to meet the requirements of the regulation and, if applicable, also national requirements. This is one of the topics the European Commission still has to establish common standards for.

In the future also manufacturers of reusable surgical instruments (class I) need to get a notified body involved. In this case the notified body limits his review solely to the aspects in regard to the re-use of the products.

Did you know about the new classification rule only for software in the MDR?

Software intended to provide data which is used to take decisions for diagnostic or therapeutic purposes will be classified into class IIa according to the new rule 10a.
This is also applicable for software which is now rather categorized as a class I product.

If such decisions have an impact that may directly or indirectly cause death or an irreversible deterioration of the state of health, the software is in class III. This is a novelty for software which is neither a part of a class III medical device nor controls or directly influences such device.

The future

There is no doubt about it: All parties involved will have to face huge challenges when the regulations will enter into force. As a manufacturer of medical devices or IVDs you should get acquainted with these new requirements as soon as possible. The earlier you do so, the better we can support you in the transition from the directives to the regulations.