

Setting the Course for Success

RAMBOLL

Bright ideas.
Sustainable change.

MIC
MEDICAL DEVICE
INNOVATION CENTER

IZKS
Interdisziplinäres Zentrum
Klinische Studien Mainz

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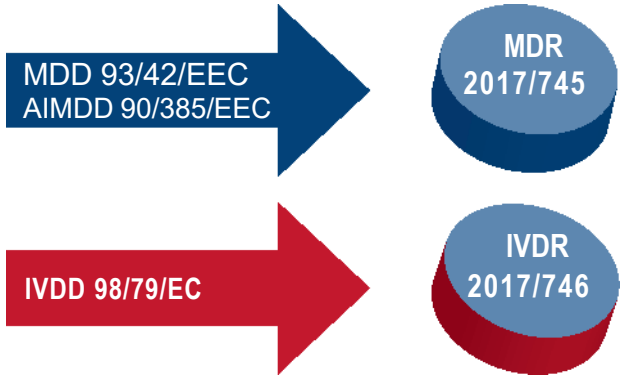
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Dear Reader,

Are you a medical device manufacturer or a developer of an innovative medical device struggling to pass bureaucratic hurdles and meet the requirements of the EU Medical Device Regulation (MDR)?

Then our full-service approach is exactly what you need. We ensure the compliance of your products with the MDR, guiding you throughout all product life cycle stages.



Medical Device Regulation MDR (EU) 2017/745

Important facts

Adopted by the European Parliament in 2017, the MDR aims to ensure and enhance patient safety by introducing more stringent requirements for medical devices. Medical device manufacturers must provide evidence of safety, performance and clinical benefits of their products and guarantee transparent monitoring and traceability of products throughout their entire lifetime. This involves preparing the technical documentation for all devices and, as a rule, performing clinical investigations for innovative or high-risk devices. After a medical device has been placed on the market, the manufacturer is obliged to implement and update the post-market clinical follow-up (PMCF) and post-market surveillance (PMS).

The MDR applies to both new and existing medical devices, including those with a former MDD CE certificate. Digital health applications (DiGA) and *in-vitro* diagnostics (IVD) are also subject to the conformity assessment procedures aiming to guarantee patient safety and therapy success. As a result, higher requirements and consistent assessment procedures need to be increasingly applied in the research and development phase to guarantee high safety, quality and performance standards of medical devices.

Key Differences at a Glance: Medical Devices vs. *In-vitro* Diagnostics

Medical Devices
are products or equipment intended for human application with or without medical purpose.

Examples:
- Implants and catheters
- Devices for injection, dressing materials and surgical suture material
- Digital health applications (DiGA)
- Ultrasound and X-ray scanners
- Disinfectants, sterilizing agents
- Transcranial brain stimulation devices

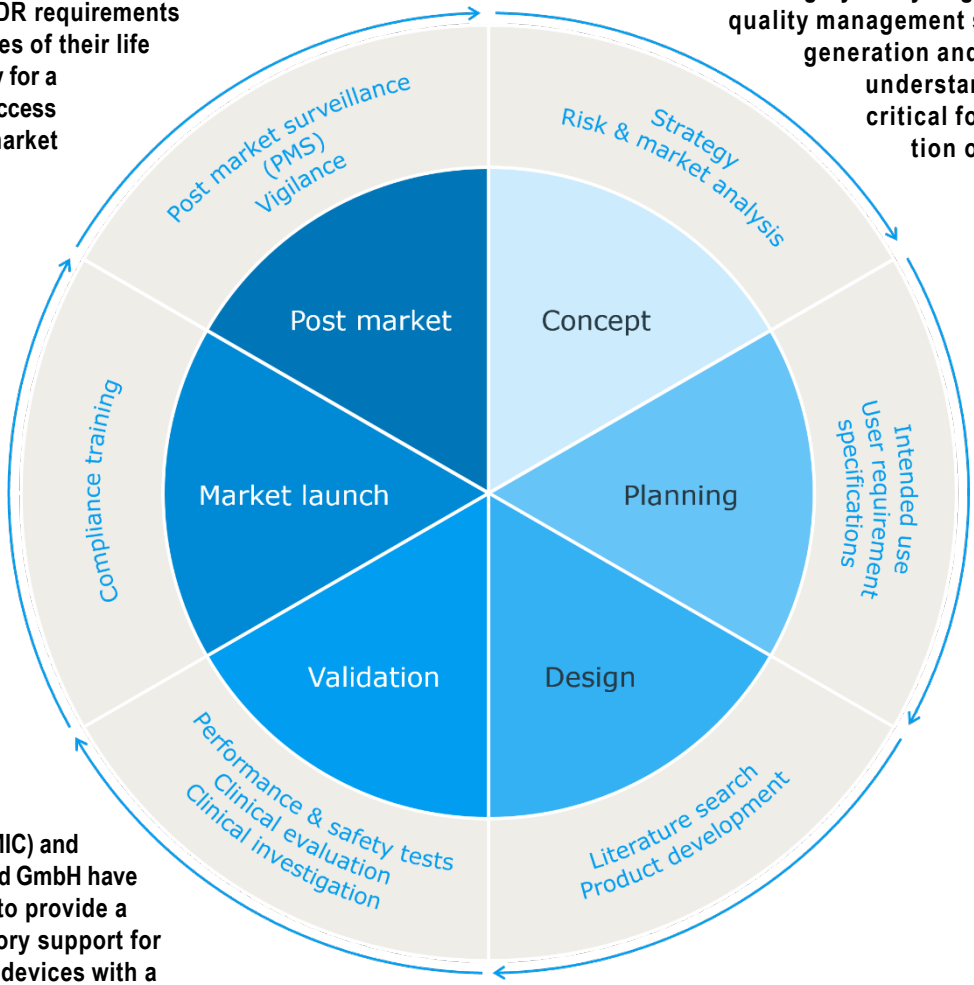
***In-vitro* diagnostics (IVD)**
are devices applied for testing human biological samples.

Examples:
- Analysis instruments (COVID PCR tests)
- Reagents and reagent products
- (Test) kits and sample containers

Staying on Top of Things: The Medical Device Life Cycle is the Key to Your Success.

As a manufacturer, you are responsible for ensuring the compliance of your medical devices with the MDR requirements throughout all stages of their life cycle. This is the key for a successful market access and continued in-market compliance.

Lateral entrants can master these challenges by thoroughly analysing the requirements of the quality management system and clinical data generation and evaluation. A thorough understanding of these factors is critical for a successful certification or in-market compliance.



The Medical Device Innovation Center (MIC) and Ramboll Deutschland GmbH have joined their forces to provide a full-service regulatory support for innovative medical devices with a special focus on product development, market approval and in-market compliance.

We help your ideas and medical devices to reach their full potential.

Taking a Closer Look at the Stages of the Product Life Cycle

Concept

The medical device development should be based on an effective strategy, risk and market analysis. This helps businesses to effectively position their products on the market by establishing their compliance with the high quality, safety and performance requirements according to the MDR. A solid conceptualisation is the basis for a successful launch and marketing of a medical device.

Planning

The intended use is crucial for the product planning since it defines the medical purpose (e.g. a special disease or health care needs) for which the medical device is designed and used. It determines various stages of the product lifecycle – from the concept, risk and market analysis to the product development and certification. The accurate identification of the intended use and documentation of the requirements are significant for ensuring the product's safety and performance within the intended use.

Design

Designing a MDR conform medical device involves thorough product development and in-depth literature search to guarantee that the future product meets user needs. Product developers need to regularly check intermediate results against the user requirements to provide its regulatory compliance. The product usability must also be considered.

Validation

The validation phase involves biological and clinical evaluation, clinical investigations as well as performance and safety tests. The evaluation and test results, in their turn, lay the ground for further validation process to verify the product compliance with the requirements of MDR and CE marking.

Market Launch

Before bringing medical devices on the market, manufactures need to ensure their compliance with the current MDR. Proper trainings for users are not only significant for safe and effective application of medical devices, but they also contribute to a successful product launch.

Post Market

Post-market surveillance (PMS) and vigilance are monitoring processes taking place after the medical device has been launched on the market. While PMS is concerned with supervising safe and effective use, vigilance focuses on reporting incidents. Both processes aim at improving the product safety for patients, allowing to identify potential risks through constant monitoring.

Our Expert Services for a Successful Development and Certification of Your Medical Devices

Ramboll

Ramboll is an independent architecture, engineering, and consultancy company employing more than 18,000 experts worldwide, creating sustainable solutions for private- and public-sector clients. Ramboll's medical device expert team provides guidance to both experienced clients and newcomers, helping them establish quality management systems and prepare the technical documentation.

Ramboll Services Overview:

- Globally compliant quality management systems (e.g. ISO 13485)
- MDR (EU) 2017/745 compliance services
- Gap analysis and tailor-made advice to close the identified deviations
- Strategic guidance on product development strategy
- Risk management implementation and moderation of risk assessments following ISO 14971
- Planning and performing biological evaluations (biocompatibility according to ISO 10993)
- Clinical evaluations in line with MDR and all applicable guidelines
- Qualification and validation of your production, quality control equipment and methods
- Advice on labelling and instructions for use
- Planning post-market surveillance (PMS)

MIC

With the MIC, manufacturers and researchers have an experienced partner providing advice on the development of new and innovative medical devices. Our clinical orientation is important when it comes to improving the efficiency of clinical research projects. Through close cooperation between industry and research, we bring together clinical competence and methodological excellence, helping to safeguard your success. While planning and conducting clinical investigations, the MIC can rely on a vast experience of the Interdisciplinary Center for Clinical Studies (IZKS) at the University Medical Center Mainz.

MIC Services Overview:

- Initial advice and expert guidance on medical devices, analysis and intellectual property
- Advice and selection of competent experts, fundings and start-up consulting, product portfolio and business case development
- Planning, conducting and completion of clinical trials according to the MDR
- Post-market clinical follow-up (PMCF and PMS)
- Product development and prototyping
- Positive impacts of medical apps (DiGA)
- Complying with the EUDAMED registration requirements
- Operational support in all aspects of the medical device vigilance system

Your Way to Us

Do not hesitate to contact us to learn more about our services in the field of medical device development and certification.

We are happy to help you!



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