MEDICAL DEVICE REGULATION (MDR)
FREQUENTLY ASKED QUESTIONS

ZOLL®

DEFINITIONS AND TIMELINES

What is MDR?

The Medical Device Regulation (MDR), or Regulation (EU) 2017/745, is a new European regulatory framework for medical devices that replaces the previous Medical Device Directive (MDD). While MDD is a directive (a guidance document) that allowed some freedom for national governments to establish their own laws, the new MDR is a regulation (a strict law). It will ensure consistency in the future across all EU countries.

After the first transition period, ending on 26 May 2021 (postponed by one year from 2020 due to the global COVID-19 pandemic), all medical devices* sold into the European Union, and the Economic operators**, must comply with MDR in order to obtain a new CE Mark. A grace period, ending May 2024, allows ZOLL® and its distributors to distribute MDD-approved products while their individual MDR applications are being reviewed.

*including all direct accessories such as cables, electrodes, sensors, etc.
**see page 2

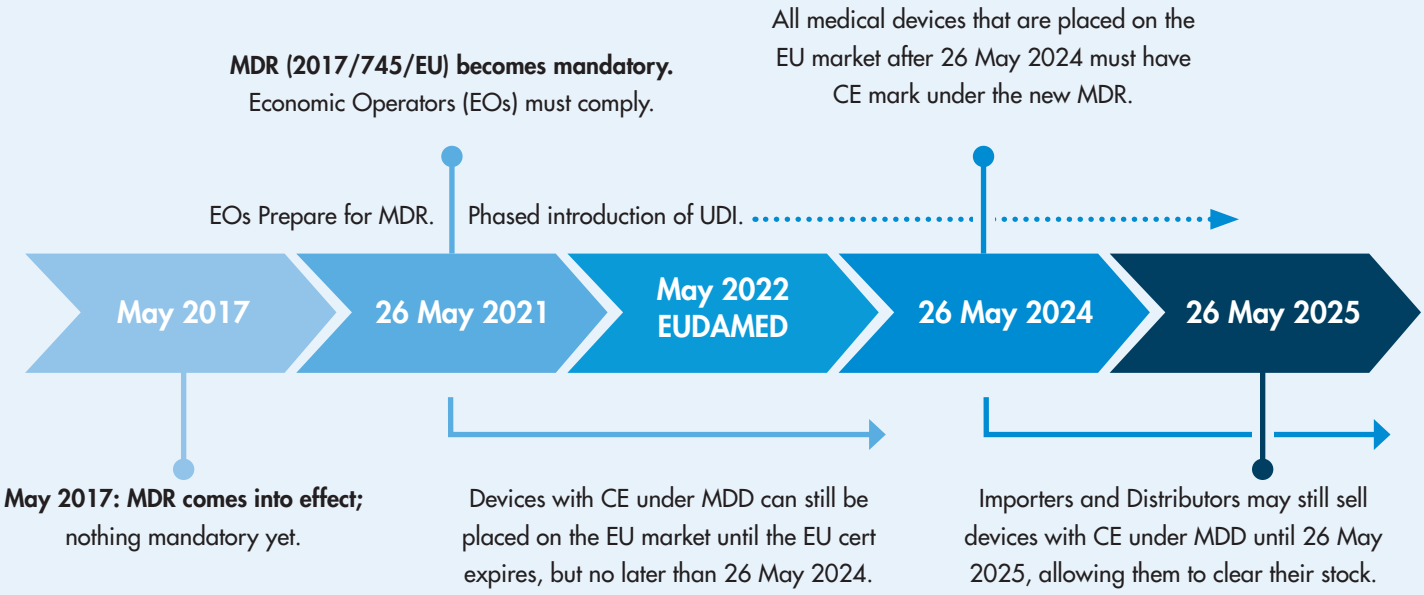
When will MDR be implemented? What are important dates to know?

The European Medical Devices Regulation (MDR) was implemented on 25 May 2017 and marked the start of a three-year transition period, originally ending on 26 May 2020. An amendment to the MDR was published in April 2020, extending the MDR Date of Application to 26 May 2021, due to the COVID-19 pandemic.

During this first transition period, manufacturers are expected to update their quality management systems to meet MDR requirements. Other players in the distribution chain, Economic Operators, must also prepare to be MDR-compliant.

Starting on 26 May 2021, new devices must meet the requirements of the MDR in order to be placed in the European market. Devices holding a certificate from a European notified body under either the Medical Device Directive (93/42/EEC) or the Active Implantable Medical Devices Directive (90/385/EEC) have an additional grace period and may continue to be placed on the market until 26 May 2024 if the manufacturer fulfils the specific prerequisite requirements drawn in the MDR.

MDR TIMELINE



Will CE Mark / Declarations of Conformity under MDD still be accepted after MDR implementation?

Yes. Unless suspended or withdrawn, all MDD Declarations of Conformity will remain valid in the transition phase until their expiration date or 26 May 2024, whichever comes first.

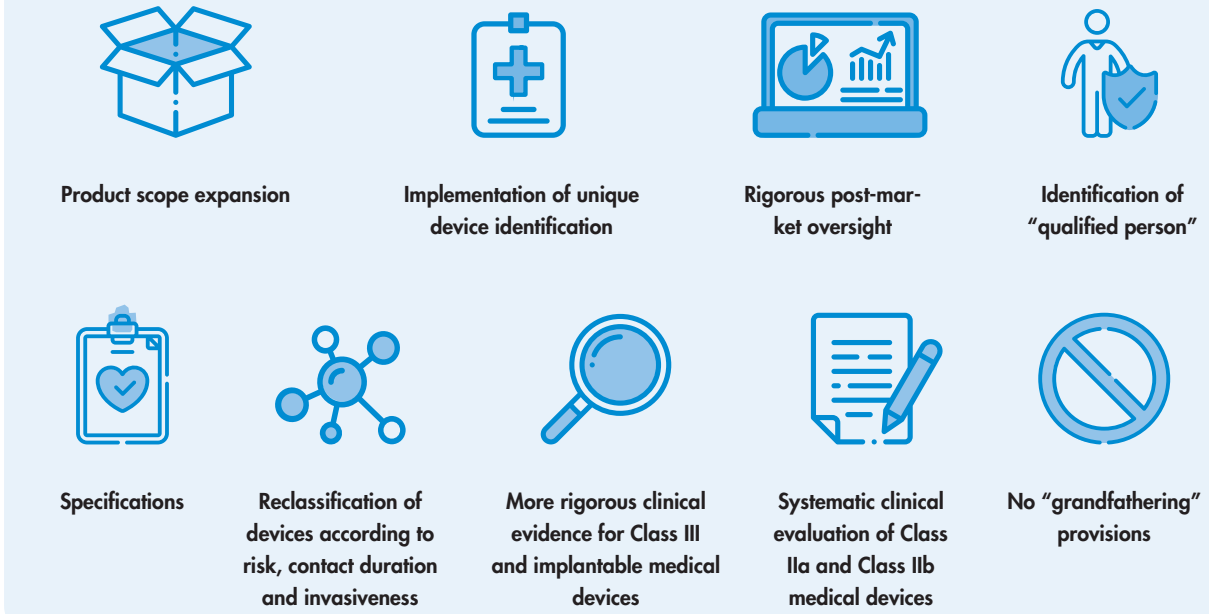
What is an Economic Operator?

Every institution/company involved in bringing a product into market is an Economic Operator (i.e., manufacturers, distributors, importers, and EC Authorised Representatives). All carry extended responsibility for the product under MDR.

What's the difference between the MDD and the new MDR?

The MDR differs in several important ways from the EU's current directives for medical devices and active implantable medical devices. The most significant changes are summarised in the following graphic:

MAJOR CHANGES UNDER MDR



- Product scope expansion – The definition of medical devices and active implantable medical devices covered under the MDR will be significantly expanded to include devices that have no intended medical purpose, such as coloured contact lenses and cosmetic implant devices and materials. Also included in the scope of the regulation are devices designed for the purpose of "prediction and prognosis" of a disease or other health condition.

- Implementation of unique device identification – The MDR mandates the use of unique device identification (UDI) mechanisms. This requirement is expected to increase the ability of manufacturers and authorities to trace specific devices through the complete supply chain, and to facilitate the prompt and efficient recall of medical devices if they are found to present a safety risk. In addition, the European Database on Medical Devices (Eudamed) is expected to be expanded to provide more efficient access to information on approved medical devices.

- Rigorous post-market oversight – The new MDR advises that there should be increased post-market surveillance authority by the notified body. Unannounced audits, along with product sample checks and product testing, will strengthen the EU's enforcement regime and help to reduce risks from unsafe devices. Annual safety and performance reporting by device manufacturers will also be required in many cases.

- Identification of "qualified person" – Device manufacturers will be required to identify at least one person within their organisation who is ultimately responsible for all aspects of compliance with the requirements of the new regulation. The organisation must document the specific qualifications of this individual relative to the required tasks. Special relief may apply to so-called micro and small enterprises.

- Specifications – The MDR plans to allow the EU Commission or expert panels to be defined to publish Common Specifications, which shall then be taken into account by manufacturers, as well as notified bodies. These Common Specifications shall exist in parallel to the Harmonised Standards and the State of the Art.

- **Reclassification of devices according to risk, contact duration and invasiveness** – The MDR will require device manufacturers to review the updated classification rules and update their technical documentation accordingly by considering the fact that Class III and implantable devices will have higher clinical requirements and a regular scrutiny process.
- **More rigorous clinical evidence for Class III and implantable medical devices** – Manufacturers will need to conduct clinical investigations in case they do not have sufficient clinical evidence to support the safety and performance claims about a dedicated device. Device manufacturers will also be required to collect and retain post-market clinical data as part of the ongoing assessment of potential safety risks.
- **Systematic clinical evaluation of Class IIa and Class IIb medical devices** – Manufacturers will need to re-evaluate their clinical data due to the new wording in the MDR regulation.
- **No "grandfathering" provisions** – Under the MDR, all currently approved devices must be recertified in accordance with the new requirements.

Will there be a difference in CE marking of a medical device?

CE Marking – Under the Medical Device Directive (MDD), companies create and store documentation that shows compliance with required standards. They then "self-certify" compliance and undergo audits by a European "notified body" to ensure that all documentation is in place in order to get to market.

The MDD is focused on the pre-approval stage of medical device manufacturing (how to go to market and obtain CE marking), whereas the **new MDR is putting emphasis on the responsibility of medical device companies for their products throughout the whole product lifecycle.**

Under the Medical Device Regulation (MDR), there is a higher level of scrutiny by these notified bodies and increased clinical evidence is required. The key focus of the MDR is to ensure patient safety.
In addition, the MDR requires:
- Individual device level approval by a third party (notified body)
- More stringent documentation
- Stricter control and annual reporting with device traceability (unique device identifier)
- Tracking by resellers

What are the benefits of MDR?

- Unified rules and governance for medical devices throughout the European Union
- Improved manufacturing standards, certifications, and quality assurance
- Greater control over safety and efficacy of medical devices and their benefits for patients (therapy effectiveness, acceptable benefit-risk ratio, etc.) to prevent potentially harmful devices from entering patient environments
- Improved transparency and traceability (e.g., for corrective actions; Unique Device Identifiers)
- Public availability of the EUDAMED database (European database on medical devices)
- Increased clinical investigation requirements to manage risk and help ensure patient safety
- Reinforced surveillance throughout the entire medical device lifecycle

ZOLL PRODUCTS AND MDR

How will MDR impact ZOLL as a manufacturer?

As a manufacturer of medical devices, ZOLL must and will make all efforts to comply with the new requirements, including:

- Manufacturers must update their Quality Management System and Technical Documentation
- Manufacturers must meet stricter requirements for Pre-Market Approval (CE marking), especially regarding clinical evidence:
    - » Under MDD, clinical justifications based on device equivalence was standard practice, resulting in many "me too" companies and products
    - » Under MDR, claiming equivalence will be less acceptable, especially for high-risk devices
- Manufacturers need to meet stricter requirements for Post-Market Surveillance, including:
    - » Complaint-based trend data and analysis (annual review)
    - » Post-Market Clinical Follow-up (annual review)
- Each device must have an UDI (Unique Device Identifier)
- All companies and devices must be registered in EUDAMED – registry of manufacturers, importers and devices – for public transparency

What is ZOLL doing to ensure compliance with MDR?

ZOLL Medical Corporation has received recertification of CE marked products under the MDD, valid until 26 May 2024. We expect that recertification under new MDR of all our CE marked products will be completed before 26 May 2024, to ensure seamless continuance.

To achieve this, ZOLL has created dedicated project teams and put robust plans in place. The project teams have been working to achieve the following goals:

- Ensuring that we have a thorough understanding of the new regulations and the changes from the current Medical Devices Directive
- Conducting a gap assessment to review current products against the new regulations. This assessment considers the reclassification of certain product groups as well as MDR's wider definition of a medical device
- Ensuring MDR compliance for all processes

Is ZOLL ready for MDR and will our customers see the impact of MDR on products and parts that they currently purchase from ZOLL?

Having already successfully implemented similar changes to meet requirements issued by the U.S. Food and Drug Administration (FDA), ZOLL is confident that we have the documentation, clinical evidence and quality systems in place to satisfy the requirements of MDR as well. We expect the new CE marks/Declarations of conformity under MDR prior to 26 May 2024.

ZOLL has also received recertification of CE marked products under the MDD, valid until 26 May 2024. No interruption in product availability is expected.

Can customers continue using their current devices while they make transition plans?

Yes. Customers can continue to use their current devices (with valid CE mark under MDD) as long as service and accessories are available.

Where can I find an overview of all products approved under the MDR?

All registered products will be published in the European Database on Medical Devices (EUDAMED), which is expected to be available in May 2022. This database will provide information about medical devices, their manufacturers, and authorised representatives, as well as data related to certificates, clinical evidence, suspension, and modifications. It will also provide data obtained in accordance with the vigilance procedure on incidents or near-incidents which occur during use of medical devices.
The vigilance module will report to EU Member States on incidents and near-incidents using electronic mail. The public part of the EUDAMED database is expected to provide only a subset of the data stored.

How can I recognise when a product's CE mark is under MDD or MDR?

Check the Declaration of Conformity for your product. The DoC is included with every product shipped. If a customer is unable to find a DoC, please contact Tech Service to request it based on the device's serial number.

ZOLL BUSINESS PARTNERS AND THIRD PARTIES

How does MDR affect ZOLL importers and business partners?

ZOLL importers and business partners will have increased responsibility for:

- Confirming device compliance by checking products for CE marking, Declarations of Conformity and UDIs (Unique Device Identifications) and informing importers, EC-REPs and manufacturers of any non-conformities
- Ensuring that storage or transport conditions comply with the conditions set by the manufacturer
- Checking to ensure that importer complies with the regulations
- Implementing corrective actions if needed
- Tracking installed base
- Maintaining a registry of complaints, incidents, non-conforming devices, corrective actions and withdrawals, and returned devices and informing manufacturers, importers and EC-REPs, and providing information upon request
- Conducting (unannounced) audits by competent authorities to verify compliance and imposing penalties in case of non-conformities

Will ZOLL have new requirements for Business Partners/Distributors?

Yes. ZOLL is updating its partnership contracts to reflect these changes.

Will third-party accessory providers be required to abide by the MDR?

Each manufacturer is responsible for meeting the requirements of the MDR. ZOLL has no influence on the processes of third-party providers. Customers should be aware that if a device is not MDR-approved, the accessories necessary for that device may no longer be supported by the manufacturer. In addition, any accessories purchased via third-party providers or online are purchased at the customer's own discretion.

For any additional questions, please contact us: EUMDR@zoll.com

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