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MEDICAL DEVICE REGULATION (2017/745) FOR THE MEDICAL INDUSTRY

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INTRODUCTION

In contrast to the previous EU regulation, the Medical Device Directive (MDD), which had the character of a guideline, the Medical Device Regulation (MDR), as a binding legal standard, places high requirements on device manufacturers with regard to production, documentation and, above all, electrical safety (including protection against electric shock). Many of the devices currently on the market fall short of completely fulfilling these requirements.

Many companies are therefore considering whether they should requalify their current devices, or take them off the market once the MDD expires. The IEC 60601 standard contained in the MDR also poses particular technical challenges for manufacturers.

The stringent and additional requirements of MDR can cost manufacturers a significant amount of time, effort and money. In some cases, this can even lead to new projects, which may have otherwise been deemed worthwhile, being shelved in the medium term.

However, this does not have to be the case. Find out in the following article how solutions can be found for the problems mentioned.

VALID DEADLINES AND DEADLINE EXTENSIONS

The deadlines in connection with the MDR have already been postponed or extended several times. The following chart shows the most important deadlines currently in force:

The new Medical Devices Regulation was adopted on 05.05.2017 and has been legally binding since 26.05.2021.

The original deadline of May 26, 2024 for the recertification of existing medical devices was extended until December 31, 2027 (for Class III and IIb medical devices) or December 31, 2028 (for all other products), depending on the risk class of the device.

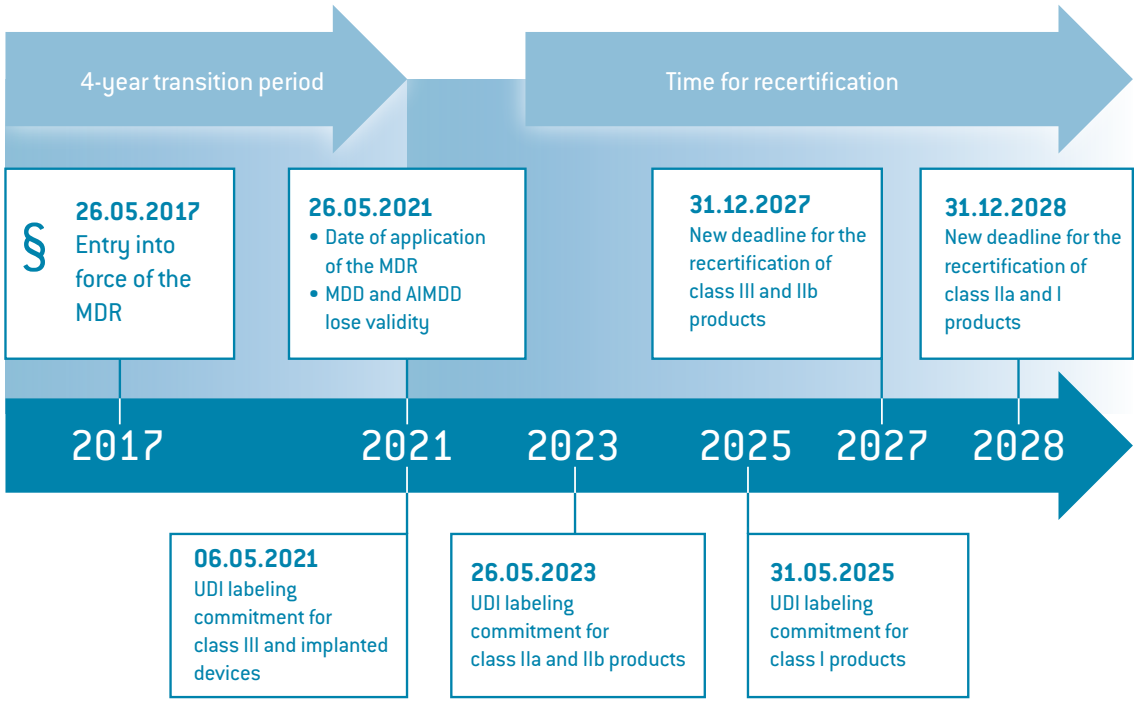

Fig 1. Timeline for the introduction of MDR and UDI

HURDLES ON THE PATH TO RECERTIFICATION

Despite the important deadline extension, many companies are reluctant to extend, or in some cases even continue the production of their legacy medical devices due to the associated costs of recertification.

There are various reasons for this: On the one hand, it is difficult to carry out a profitability analysis if potential sales figures are hard to determine. As a result, it remains unclear whether the comparatively high expense for recertification can be amortized during the remaining life-cycle span of the legacy product in question. Another problem is that the certification processes are currently very lengthy.

Giving up Europe as a sales market is out of the question for most companies. The enormous sales potential and high demand for medical devices promise good revenues in the long term. As a result, many companies are looking for a solution that is as uncomplicated and quick to implement as possible.

Fig 2. Open reduction for plate fixation of a fractured ulna bone

Fig 3. Gastroenterology examination

ODU MAKES COMPLIANCE WITH IEC 60601 EASIER

ODU supports its customers in many ways to ensure compliance with the MDR regulations.

IEC 60601 requirements and designs vary depending on the application area, and in many cases an ODU connector can provide the right solution. In the case of the electromagnetic compatability required by IEC 60601-1-2, for example, standard connectors from the ODU MINI-SNAP® portfolio, or specially adapted plastic connectors from the ODU MEDI-SNAP® portfolio fulfill the shielding requirements.
ODU components can also meet the requirements for high-frequency surgical equipment and defibrillators set out in IEC 60601-2-2 and IEC 60601-2-4.

Moreover, ODU can provide a solution that fulfills the requirements for the „Means of Patient Protection“ (MOPP) and „Means of Operator Protection“ (MOOP) as defined in IEC 60601-1: In many constellations, a simple replacement of the electrical connector is sufficient to meet the requirements for safety against electric shock. The original design of the product can thus be retained. This significantly reduces the effort required to recertify existing devices, as no extensive changes to the device itself are necessary.

This reduces both the costs and the duration of the project. As a result, the business case for recertification may well turn positive as profitability returns.

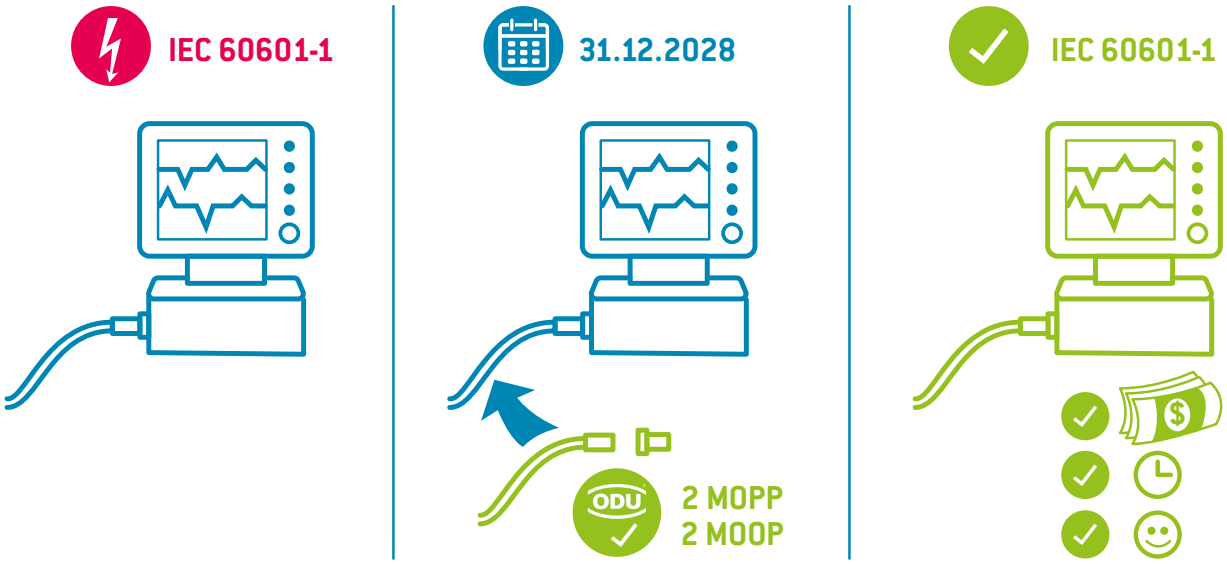

Fig 4. Benefits of compliance with IEC60601-1 for the protection of patients and users

As a component manufacturer, ODU offers its customers the option of purchasing high-quality connectors in which touch protection in accordance with IEC 60601-1 is already integrated (2 MOPP and 2 MOOP = Means of Patient/ Operator Protection). This means that existing devices can be recertified without major effort when redesigning device components, or new devices can be made even safer.

For a more detailed explanation of how ODU connectors enable compliance with IEC 60601-1, take a look at our

White paper on the topic IEC 60601-1.

OTHER ASPECTS OF MDR

In addition to making compliance with IEC 60601 easier, there are other aspects of the MDR where ODU supports its customers: In many cases the inherent design, manufacturing and logistic processes of the connector being supplied help the device manufacturer fulfill MDR requirements. ODU can support with the following aspects:

Technical documentation
Manufacturers must provide comprehensive technical documentation containing all relevant information on the design, manufacture, safety, performance and clinical evaluation of the device.

Risk management
A systematic approach to the identification, assessment and control of risks associated with the use of electrical equipment. The risk assessment for each product group is carried out in accordance with EN ISO 14971.

Change management (especially in accordance with DIN EN ISO 13485:2021)
Changes to products or processes that affect quality require classification into two types: "major" for significant changes that require approval from authorities, and "minor" for minor changes that only need to be documented and may require general notification.

Management of CMR substances
For carcinogenic, mutagenic or reprotoxic substances (CMR) and substances with endocrine disrupting features, a maximum limit of 0.1% by mass (w/w) applies. Justification is required for higher levels and the presence of CMR substances must be labeled on the products.

Continuous traceability
In the frame of the Unique Device Identification (UDI), every medical device must have a unique label for identification. This code enables the exact traceability of a product back to the manufacturer.

Storage of technical documents:
The MDR requires the manufacturer of a medical device to provide complete documentation of the work, among other things. This also includes the archiving of documents from upstream suppliers. ODU guarantees complete data storage in accordance with customer requirements.

SUMMARY

In view of the complex requirements and challenges posed by the MDR, medical device manufacturers are facing difficult decisions with respect to product life-cycle management.

Connector manufacturers like ODU can play a decisive role in facilitating the certification process by helping the device manufacturer achieve compliance with IEC 60601, and also otherwise reducing risk in the overall supply chain. This is the case for both legacy medical devices already on the market and new medical devices being freshly introduced.

So don't hesitate to contact ODU with your MDR projects!

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THE AUTHOR

Mathias Wuttke has been active in the technical sales of medical products for over 20 years. After graduating in Electrical and Electronics Engineering from Leipzig University of Applied Sciences, he worked for various companies as a Sales Manager and Account Manager. He has been working for ODU as Business Development Manager in the medical sector since 2018. In the frame of his work, he supports new and existing customers all over the world with the insertion of connectors and cable assemblies. He comes into contact with the topic of MDR and its implementation on a daily basis.

COMPANY PROFILE ODU

ODU is one of the leading international suppliers of connector systems and employs around 2,700 employees worldwide. In addition to its company headquarters in Muehldorf a. Inn. Further production and product development sites are located in Sibiu / Romania, Shanghai / China, Tijuana / Mexico and Camarillo / USA.

ODU combines all relevant areas of expertise and key technologies including design and development, machine tooling and special machine construction, molding, stamping, turning, surface engineering, assembly, and cable assembly.

The ODU group sells its products globally through an international distribution network This includes its own sales companies in China, Denmark, Germany, France, Hong Kong, Italy, Japan, Korea, Austria, Sweden, the UK and the USA, as well as numerous global sales partners.

Connectors from ODU ensure the reliable transmission of power, signals, data and media in numerous demanding application areas: for example in medical technology, military and security technology, automotive as well as in industrial electronics or test and measurement.

INTERESTED?

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