

# European Union Compliance Times

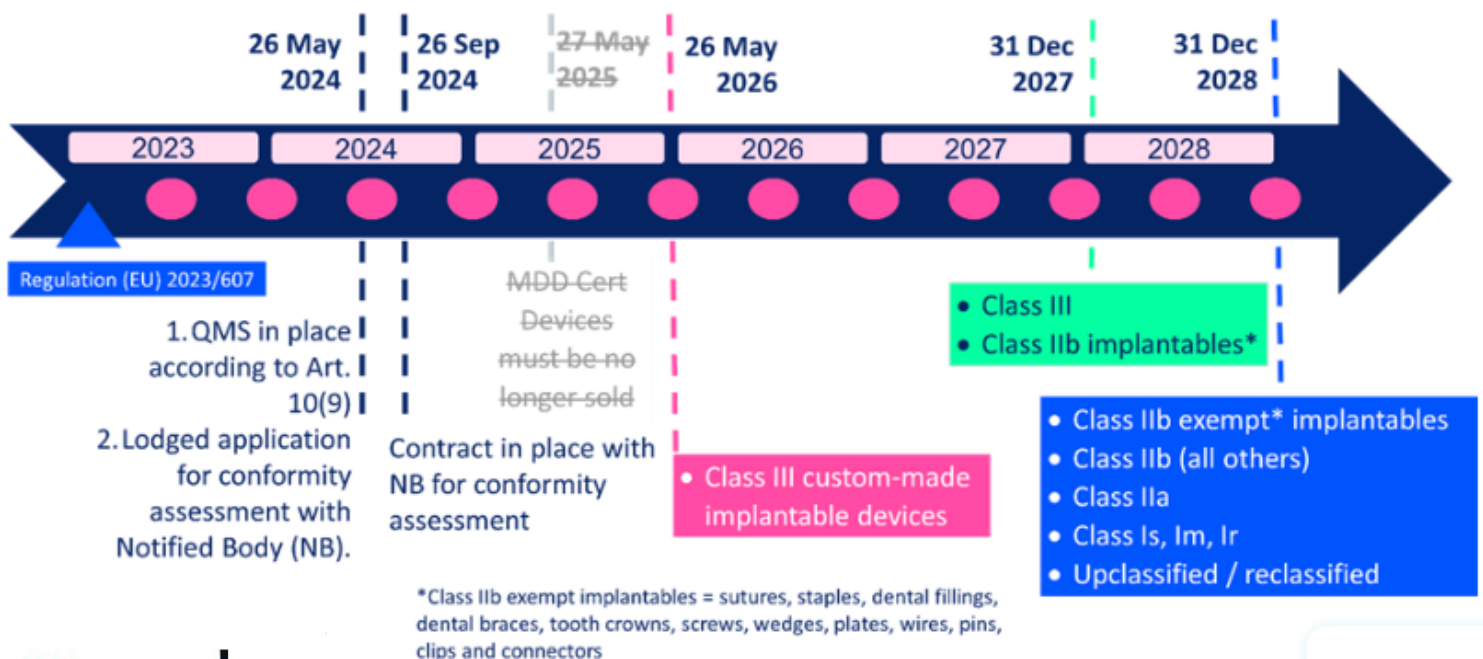
As you probably know, the EU MDR was adopted in April 2017 and entered into force in May 2017, replacing the previous Medical Device Directive 93/42 EEC (MDD) and Active Implantable Medical Device Directive (AIMDD). Medical device manufacturers had until May 26, 2021 to comply with the EU MDR.

Due to pressures in the regulatory process, it has not been possible for all previously MDD CE Marked devices to be re-certified to the EU MDR. This has led to concerns that supplies of critical devices will be hindered leading to shortages and so on 20 March 2023, Regulation ((EU) 2023/607) amending the EU MDR and IVDR was published.

The amendment extends the EU MDR transition timelines while also recognising valid previously issued MDD, AIMDD Certificates for the duration of those longer transition timelines. This allows manufacturers to continue placing their devices on the market based on compliance to the Directives while they continue the transition of their devices to the EU MDR.

**It is important to note that the longer transition timelines apply only to devices that are transitioning to EU MDR and meet other specific conditions set out in the Regulation.**

A staggered and conditional extension of the transition period was introduced according to the type of device as presented below:



Manufacturers who are currently transitioning their products to MDR need to be aware of the critical deadline in May 2024 when they will be required to put in place an EU MDR QMS.

**It is essential to start the certification process well in advance to avoid any last-minute compliance issues.**

This is a summary of a very complex subject. You can find more details in our 3 part blog on the 'Crucial role of Quality Management Systems and ISO 13485 for Medical Device Manufacturers' on our website.

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