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Client Alert Commentary

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EU MDR Transitional Provisions Officially Extended

The revised provisions provide medical device and in-vitro diagnostics manufacturers with additional time to bring their product into compliance with the new EU Regulations, subject to a number of conditions.

On March 20, 2023, Regulation (EU) no 2023/607 was published in the Official Journal of the European Union, following speedy adoption by the European Parliament and Council. The new Regulation amends Regulation (EU) no 2017/745 (MDR) and Regulation (EU) no 2017/746 (IVDR) and extends the transitional periods set out under these two regulations.

In January 2023, the European Commission proposed to extend these transitional periods in order to address the rising risk of medical device (MD) shortages, resulting in particular from:

- delays in the designation of notified bodies (NB) under the MDR and IVDR, mainly due to the COVID-19 pandemic; and
- many operators not yet being ready to meet the new MDR/IVDR requirements.

Thus, many MDs whose certificates of conformity were issued under the former Medical Devices Directive (MDD), Active Implantable Medical Devices Directive (AIMDD), and In Vitro Diagnostic Devices Directive (IVDD) have now expired. Since manufacturers have been unable to recertify their MDs under the new Regulations, they can no longer place them on the market.

The medtech sector had already anticipated and discussed these issues last year. In August 2022, the Medical Device Coordination Group (MDCG) issued a first position paper setting out a list of actions intended to increase NB capacity and manufacturer readiness, so as to facilitate the transition to the MDR and IVDR within the initial transition periods. In the last trimester of 2022, the MDCG issued another position paper aiming to clarify the application of Article 97 of the MDR to legacy devices whose certificates were issued under the MDD (or AIMDD) and expired before being recertified under the MDR. This position paper, however, was only intended as a temporary solution to address the expected bottleneck of expiring certificates and, as such, the guidance should only apply to devices whose certificates have expired before March 20, 2023.

The Regulation aims to ensure patients' continued access to MDs, while guaranteeing that devices available in the EU remain safe and effective. The Regulation therefore amends the MDR's/IVDR's transitional provisions using a risk-based approach.

Most importantly, the Regulation extends the validity of certificates issued under the former Directives, subject to a number of obligations MD manufacturers must meet (see the below table for more information). The Regulation does not affect existing deadlines within the IVDR, as Regulation (EU) No. 2022/112 already amended those back in 2022 in the context of the COVID-19 pandemic. The Regulation does, however, remove the so-called "sell-off" dates which both the MDR and the IVDR initially provided, i.e., the date by which legacy devices already placed on the market before the entry into application of these regulations could continue to be made available or put into service.

<table>
<tr><th>My device is a …</th><th>My device may be placed on the market/put into service and its certificate will remain valid until …</th><th>As a manufacturer, I need to fulfill the following conditions in order to benefit from the extended deadline …</th></tr>
<tr><td>Class III custom-made implantable device</td><td>May 26, 2026
The 2025 sell-off date no longer applies.</td><td>I have submitted an application for a conformity assessment by May 26, 2024.
I have entered into an agreement for a conformity assessment with an NB by September 26, 2024.</td></tr>
<tr><td>Other Class III device
Class IIb implantable device except sutures, staples, dental braces, dental fillings, tooth crowns, screws, wedges, plates, wires, pins, clips, or connectors</td><td>December 31, 2027
The 2025 sell-off date no longer applies.</td><td rowspan="3">If my device certificate was issued under the MDD/AIMDD from May 25, 2017, was valid on May 26, 2021, and has not been withdrawn since, I must comply with the following to benefit from the extended deadline:
My device remains compliant with the MDD/AIMDD
There is no significant change in the device's design and intended purpose.
My device does not present an unacceptable risk to patients' health or safety, or to public health.
I have implemented an MDR-compliant quality management system by May 26, 2024.
I have submitted an application for a conformity assessment by May 26, 2024 (for the device itself or a device intended to substitute it), and executed an agreement for a conformity assessment with a NB by September 26, 2024.
I remain compliant with relevant MDR provisions on post-market surveillance, vigilance, and registration on Eudamed (these provisions being applicable as from May 26, 2021).
In addition to the above requirements, if my device certificate was issued under the MDD/AIMDD from May 25, 2017, was valid on May 26, 2021, and has not been withdrawn since but has expired before March 20, 2023, I must meet one of the following conditions in order to benefit from the extended deadline:
I have entered into an agreement with an NB for a conformity assessment before the certificate's expiry date; or
I have obtained a derogation under Article 59 (1) or Article 97 (1) MDR by an EU member state NCA.</td></tr>
<tr><td>Other Class IIb device
Class IIa device
Class I m and I s device (device placed on the market in sterile condition or having a measuring function)</td><td rowspan="2">December 31, 2028
The 2025 sell-off date no longer applies.</td></tr>
<tr><td>Device for which there was no NB involvement required under the MDD, with declaration of conformity was drawn up before May 26, 2021 and which now requires the involvement of an NB under the MDR</td></tr>
<tr><td>Class I device other than the categories above</td><td>My device should already have been MDR compliant by May 26, 2021.
The 2025 sell-off date no longer applies.</td><td>N/A</td></tr>
<tr><td>In-vitro diagnostic device</td><td>I do not benefit from any extended deadline, but the 2025 sell-off date no longer applies.</td><td>N/A</td></tr>
</table>

The new transitional provisions have already become applicable.

While the Regulation addresses the issue of maintaining legacy devices on the EU market, uncertainties remain as to whether NBs will have the bandwidth to assess the conformity of both existing devices and new innovative devices manufacturers are looking to place on the EU market in the coming years. This lack of NB capacity could impact European patients' access to medtech innovation in the foreseeable future.

Further, the extended deadlines within the Regulation also depend on the manufacturer meeting a number of substantial conditions, e.g., implementing a quality management system. Manufacturers must therefore sufficiently anticipate these new requirements and have or develop the capacity to meet them within little more than a year. As such, manufacturers which have not yet started transitioning toward the new MDR/IVDR will unlikely benefit from these extended deadlines.

The European Commission is expected to publish a Q&A document containing additional details on how relevant stakeholders should interpret and implement the updated transitional provisions. Competent authorities should also provide additional guidance at national level in the coming months.

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