

MDCG 2022-11

MDCG Position Paper

Notice to manufacturers to ensure timely compliance with MDR requirements

JUNE 2022

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

With the adoption of Regulations (EU) 2017/745 (MDR) and 2017/746 (IVDR), the regulatory framework for medical devices and *in vitro* diagnostic medical devices (IVD) has changed significantly. The main objectives of these two regulations are to “*establish a robust, transparent, predictable and sustainable regulatory framework for medical devices and in vitro diagnostic medical devices which ensures a high level of safety and health whilst supporting innovation*”.

Five years have passed since their adoption and the system is being implemented including the development of the joint assessment process for designation of notified bodies, designation of expert panels, publication of harmonised standards as well a large number of guidance documents seeking to help economic operators to comply with their obligations under the Regulations.

Data provided in April 2022 by notified bodies show that more than 90% of currently valid AIMDD/MDD certificates will expire in 2023-2024¹. To date, 30 notified bodies are designated under the MDR, managing around 80% of current AIMDD/MDD certificates².

While the MDR has been applicable since 26 May 2021, it provides for transitional provisions allowing medical devices certified under the AIMDD and MDD to be placed on the market until the expiry date of relevant certificates and no later than 26 May 2024. The transition period intends to give further time to the system to prepare and to get ready, for example time for manufacturers to prepare their quality management system (QMS) and technical documentation before applying to a notified body. This step should not be perceived as a “grace period” to postpone the entering into application of the new rules. At this stage, data collected by notified bodies, and presented to competent authorities in December 2021, shows that nearly 37% of manufacturers’ applications have been refused on the basis of incomplete applications, underlining an overall lack of manufacturers’ preparedness³. In April 2022, 75% of notified bodies indicated that more than 50% of the submitted applications were deemed incomplete⁴.

From 27 May 2024, the MDR will be fully applicable to all medical devices. Manufacturers are responsible to ensure that their devices comply with the MDR as from the end of the transition period. From that date, medical devices not certified under the MDR will have no access to the EU market.

It should be noted that around 70% of AIMDD/MDD certificates will expire in 2024⁵ (by 26 May 2024 at the latest). Manufacturers should take into consideration that it

¹ Notified Bodies survey, April 2022

² Notified Bodies survey, April 2022

³ NBCG-Med information provided in December 2021

⁴ Notified Bodies survey, April 2022

⁵ Notified Bodies survey, April 2022

might not be possible that notified bodies designated under the MDR would be able to assess all corresponding files within the first months of 2024.

Derogation from the conformity assessment procedure in accordance with Article 59 of the MDR has been mentioned as a possible remedy in case transition from AIMDD/MDD to MDR is not completed in time. It is important to stress that derogations may be granted by competent authorities only if the use of the device concerned is in the interest of public health, patient safety or patient health. This mechanism should not be considered as a solution for cases of late application to a notified body for conformity assessment or delays in the conformity assessment procedure. Economic grounds alone cannot justify a derogation under Article 59 MDR either. Also other mechanisms provided by the MDR in chapter VII (e.g. to deal with formal non-compliant products) will only be applicable for devices for which the manufacturer can demonstrate that he has undertaken all reasonable efforts to successfully conclude the transition to the MDR, including update of its QMS, in time. In this context, it is expected that the manufacturer has submitted an application to a notified body for certification in compliance with the MDR at least one year before the expiry date of the MDD/AIMDD certificate.

Therefore and in order to ensure that devices can continue to be placed on the market and to avoid shortages of medical devices, it is essential that all manufacturers adjust their system, finalise transition to the MDR and apply to a notified body, submitting complete and compliant applications, as soon as possible and well in advance of the end of the transition period to ensure timely compliance with the MDR.

