MDCG 2022-18 ADD.1

MDCG Position Paper on the application of Article 97 MDR to legacy devices for which the MDD or AIMDD certificate expires before the issuance of a MDR certificate

Addendum 1 - June 2023

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.

The position paper MDCG 2022-18 was published in December 2022 to provide a uniform approach to the application of Article 97 of Regulation (EU) 2017/745 on medical devices (MDR) in situations where a certificate issued under Directive 93/42/EEC (MDD) or Directive 90/385/EEC (AIMDD) has expired or expires before issuance of the necessary certificate(s) in accordance with the MDR. The use of Article 97 MDR in those situations was meant to be a temporary solution. The goal of the position paper MDCG 2022-18 was to contribute to avoiding disruption of supply of devices on the EU market needed for health systems and patients.

With the entry into force of Regulation (EU) 2023/607 on 20 March 2023[1], the MDR transitional period and the validity of MDD/AIMDD certificates have been extended, provided that the conditions in the amended Article 120 MDR are met.

Regulation (EU) 2023/607 has averted the imminent risk of shortages of critical legacy devices related to the expiry of MDD/AIMDD certificates.

The MDCG therefore considers that the application of Article 97 MDR in accordance with MDCG 2022-18 to situations where a MDD/AIMDD certificate has expired prior to the issuance of a MDR certificate has achieved its objective and is not relevant any more.

The MDCG recommends that national CAs limit the application of Article 97 MDR as set out in MDCG 2022-18 to very exceptional situations, e.g. where the national competent authority (CA) has received information justifying the application of Article 97 MDR prior to 20 March 2023.

Where, after 20 March 2023, a competent authority has required or requires a manufacturer, in accordance with Article 97 MDR, to carry out the applicable conformity assessment procedure, the condition set out in Article 120(2), second subparagraph, point (b), of the MDR is not met. Therefore, the expired certificate will not be considered valid and the extended transitional period set out in Article 120(3a) MDR does not apply.

[1] Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices (OJ L 80, 20.3.2023, p. 24).