

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (Text with EEA relevance)

CHAPTER X

FINAL PROVISIONS

Article 112

Repeal

Without prejudice to Articles 110 (3) and (4) of this Regulation, and without prejudice to the obligations of the Member States and manufacturers as regards vigilance and the obligations of manufacturers as regards the making available of documentation, under Directive 98/79/EC, that Directive is repealed with effect from 26 May 2022 with the exception of:

- (a) Article 11, point (c) of Article 12(1) and Article 12(2) and (3) of Directive 98/79/EC, and the obligations relating to vigilance and performance studies provided for in the corresponding Annexes, which are repealed with effect from the later of the dates referred to in Article 113(2) and point (f) of Article 113(3) of this Regulation; and
- (b) Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC, and the obligations relating to registration of devices and economic operators, and certificate notifications provided for in the corresponding Annexes, which are repealed with effect from 18 months after the later of the dates referred to in Article 113(2) and point (f) of Article 113(3) of this Regulation.

As regards the devices referred to in Article 110(3) and (4) of this Regulation, Directive 98/79/EC shall continue to apply until 27 May 2025 to the extent necessary for the application of those paragraphs.

Decision 2010/227/EU adopted in implementation of Directives 90/385/EEC, 93/42/EEC and 98/79/EC shall be repealed with effect from the later of the dates referred to in Article 113(2) and point (f) of Article 113(3) of this Regulation.

References to the repealed Directive shall be understood as references to this Regulation and shall be read in accordance with the correlation table laid down in Annex XV.

Status:

Point in time view as at 05/04/2017. This version of this provision has been superseded.

Changes to legislation:

There are currently no known outstanding effects for the Regulation (EU) 2017/746 of the European Parliament and of the Council, Article 112.