

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 III

IDENTIFICATION AND TRACEABILITY OF DEVICES, REGISTRATION OF DEVICES AND OF ECONOMIC OPERATORS, SUMMARY OF SAFETY AND CLINICAL PERFORMANCE, EUROPEAN DATABASE ON MEDICAL DEVICES

Article 26

Registration of devices

1 Before placing a device on the market, the manufacturer shall, in accordance with the rules of the issuing entity referred to in Article 24(2), assign a Basic UDI-DI as defined in Part C of Annex VI to the device and shall provide it to the UDI database together with the other core data elements referred to in Part B of Annex VI related to that device.

2 For devices that are the subject of a conformity assessment as referred to in Article 48(3) and (4), the second subparagraph of Article 48(7), Article 48(8) and the second subparagraph of Article 48(9), the assignment of a Basic UDI-DI referred to in paragraph 1 of this Article shall be done before the manufacturer applies to a notified body for that assessment.

For the devices referred to in the first subparagraph, the notified body shall include a reference to the Basic UDI-DI on the certificate issued in accordance with point (a) of Section 4 of Annex XII and confirm in Eudamed that the information referred to in Section 2.2 of Part A of Annex VI is correct. After the issuing of the relevant certificate and before placing the device on the market, the manufacturer shall provide the Basic UDI-DI to the UDI database together with the other core data elements referred to in Part B of Annex VI related to that device.

3 Before placing a device on the market, the manufacturer shall enter or, if already provided, verify in Eudamed the information referred to in Section 2 of Part A of Annex VI, with the exception of Section 2.2 thereof, and thereafter shall keep the information updated.