

Commission Decision of 19 April 2010 on the European Databank
on Medical Devices (Eudamed) (notified under document
C(2010) 2363) (Text with EEA relevance) (2010/227/EU)

Article 2

Member States shall ensure that the data referred to in points (a) and (b) of Article 10b(1) of Directive 90/385/EEC, points (a), (b) and (c) of Article 14a(1) of Directive 93/42/EEC and points (a), (b) and (c) of Article 12(1) of Directive 98/79/EC, are entered into Eudamed in accordance with the Annex to this Decision.

For clinical investigations Member States shall ensure that an extract of the notifications referred to in Article 10(1) of Directive 90/385/EEC and in Article 15(1) of Directive 93/42/EEC, as well as the information referred to in Article 10(3) and (4) of Directive 90/385/EEC and in Article 15(6) and (7) of Directive 93/42/EEC are entered into Eudamed in accordance with the Annex to this Decision.

Changes to legislation:

There are outstanding changes not yet made to Commission Decision of 19 April 2010 on the European Databank on Medical Devices (Eudamed) (notified under document C(2010) 2363) (Text with EEA relevance) (2010/227/EU). Any changes that have already been made to the legislation appear in the content and are referenced with annotations.

[View outstanding changes](#)

Changes and effects yet to be applied to :

- Decision repeal by [EUR 2017/746](#) Regulation
- Decision revoked by S.I. 2002/618, reg. 4I (as inserted) by [S.I. 2019/791](#) reg. 3(7)