

MDCG 2019-4

Timelines for registration of device data elements in EUDAMED

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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.

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“With regard to timelines for device registration, the text of the MDR presents an inconsistency. On the one hand, Article 123(3)(d) lists the full Article 29 as being applicable from the application dates or, if EUDAMED is not functional on time, six months after the date of publication of the notice referred to in Article 34(3). On the other hand, Article 123(3)(e) grants an additional 18-month transitional period for obligations contained in Article 29(4).

Taking into account:

- the declared will of the co-legislator to grant an 18-month additional transitional period for device registration and registration of certificates,
- the logical correspondence and complementary character of device data elements in Part A (Section 2) and Part B of Annex VI,
- the need to ensure that information on devices in EUDAMED is not displayed to public in a partial or misleading nature,

the obligation for registration in EUDAMED of device data elements listed in both part A, Section 2, and Part B of Annex VI, shall be applicable as from the timelines indicated in Article 123(3)(e) (meaning from 18 months after the general application date or, if EUDAMED is not fully functional on time, from 24 months after the date of publication of the notice referred to in Article 34(3)).

This is without prejudice to the fact that the obligation related to the operation of assignment of Basic UDI—DI and UDI-DI to devices remains applicable as from the general application dates.

This is also without prejudice to the fact that at any time after the general application date, for MDR compliant devices, the full registration of devices (Article 29) remains a pre-condition for the possible registration of their relevant serious incident in EUDAMED

These considerations apply *mutatis mutandis* to the IVDR”.

