ANNEX

TABLE DETAILING THE MANDATORY DATA FIELDS IN THE RESPECTIVE MODULE IN THE EUDAMED DATABANK ACCORDING TO THE OBLIGATIONS ARISING FROM DIRECTIVES 93/42/EEC, 90/385/EEC AND 98/79/EC

Directive 93/42/EEC	**Minimum data required for Eudamed data entry**
Article 14a(1)(a) and Article 14(1) and (2)	1. Actor (manufacturer/authorised representative): (a) Name; (b) Street; (c) Locality; (d) Postcode; (e) Country; (f) Phone or E-mail; (g) Role. 2. Device: (a) Internationally recognised nomenclature code (for data generated after 1 May 2011); (b) Device Name/Make or, where not available, generic name.
Article 14a(1)(b)	3. Certificate: (a) Certificate number; (b) Certificate type; (c) Date of Issue; (d) Expiration Date; (e) Manufacturer and, if applicable, authorised representative (see fields under 1. Actor); (f) Notified Body (selected from system); (g) General Scope description and, where applicable, details on device (see fields under 2. Device); (h) Status and, where applicable, reasons for decision of Notified Body.
Article 14a(1)(c) and Article 10(3)	4. Incident (National Competent Authority Report): (a) Competent Authority reference; (b) Manufacturer, where applicable authorised representative (see fields under 1. Actor); (c) Manufacturer contact; (d) Manufacturer reference/Field Safety Corrective Action (FSCA) nr.;

	(e) Device (see fields under 2. Device), plus where applicable lot number, serial number, software version; (f) Notified Body (selected from system); (g) Device known to be in the market in; (h) Confidential; (i) Complete investigation; (j) Background Information (Description); (k) Conclusion; (l) Recommendation; (m) Action and action description.
Article 14a(1)(d) and Article 15(1), (6) and (7)	5. Clinical Investigation: (a) Manufacturer, where applicable authorised representative (see fields under 1. Actor); (b) Device (see fields under 2. Device); (c) Title of investigation; (d) Protocol number; (e) Primary objective; (f) Competent Authority Contact for this Clinical Investigation; (g) Decisions taken by Competent Authority pursuant to Article 15(6), date of decision and grounds; (h) Early termination on safety grounds pursuant to Article 15(7), date of decision and grounds.
Directive 90/385/EEC	**Minimum data required for Eudamed data entry**
Article 10b(1)(a)	6. Certificate (see fields under 3. Certificate)
Article 10b(1)(b) and Article 8(3)	7. Incident (see fields under 4. Incident)
Article 10b(1)(c) and Article 10(1), (3) and (4)	8. Clinical Investigation (see fields under 5. Clinical Investigation, (a) to (f)): (a) Decisions taken by Competent Authority pursuant to Article 10(3), date of decision and grounds; (b) Early termination on safety grounds pursuant to Article 10(4), date of decision and grounds.
Directive 98/79/EC	**Minimum data required for Eudamed data entry**

Article 12(1)(a) and Article 10(1), (3) and (4) and Annex VIII (4)	9. Actor (for all *in vitro* diagnostic medical devices (IVD's): Address of manufacturer, respectively authorised representative (see fields under 1. Actor). 10. Device: For all IVD's (a) Device (see fields under Device 2.); (b) Information on whether device is 'new'; (c) Discontinuation of placing on the market. In addition for Annex II and self-testing (d) Outcome of performance evaluation, where applicable; (e) Certificates (see fields under 3. Certificate); (f) Conformity with Common Technical Specifications, where applicable; (g) Identification of device.
Article 12(1)(b)	11. Certificate (see fields under 3. Certificate)
Article 12(1)(c) and Article 11(3)	12. Incident (see fields under 4. Incident)

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)