A: Relevant legislation

The legislation stated below constitutes the framework for performance of clinical investigations involving the use of medical devices. The Inspectorate maintains supervision over compliance with this legislation.

- Medical device regulation (*"Medische hulpmiddelen verordening"*, MDR, link)
- In vitro diagnostic regulation (*"In-vitro diagnostica verordening"*, IVDR, link)
- Medical Devices Act (*"Wet op de medische hulpmiddelen"*, WMH; link)
- Medical Devices Decree (*"Besluit medische hulpmiddelen"*, BMH; link) and Active Implants Decree (*"Besluit actieve implantaten"*, BAI; link)
- Medical Research (Human Subjects) Act (*"Wet medisch-wetenschappelijk onderzoek met mensen"*, WMO; link)
- Medical Treatment Contracts Act (*"Wet op de geneeskundige behandelovereenkomst"*, WGBO; link)
- EU Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (link) and EU Council Directive 90/385/EEC of 20 June 1990 concerning active implantable medical devices (link), and EU Council Directive 98/79/EC of 27 October 1998 concerning in vitro diagnostic medical devices (IVDD, link);
- MEDDEV 2.7/3 concerning the reporting of Serious Adverse Events (SAEs) in the case of non-CE marked devices or of medical devices used outside the intended use(s) covered by the CE marking (link)
- MEDDEV 2.12/1 concerning the reporting of SAEs that occur during clinical investigations with products already CE-marked and that are also in use in accordance with the information for which the marking was issued (link)
- ISO 14155 (link (paid))

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