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 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)
- 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))