

B: Clinical investigations involving the use of medical devices – regime

A medical device may not be put on to the market in Europe unless it has been provided with CE marking. A manufacturer may provide a medical device with CE marking only if it meets the Essential Requirements stated in Annex I to European Directive 93/42/EEC or European Directive 90/385/EEC. For this purpose, the manufacturer must perform or commission conformity evaluation procedures. The manufacturer must instruct a Notified Body to check whether the medical device meets the Essential Requirements.

A manufacturer may not deliver a medical device that is not CE-marked, and such a medical device may not be applied.

An exception is where the manufacturer designates the medical device as a medical device intended for a clinical investigation. Under this exception, the law allows the manufacturer to perform a clinical investigation prior to putting the medical device on to the market for the purpose of obtaining data that may be used to ensure compliance with the Essential Requirements. The exception allowing a manufacturer to supply medical devices without CE marking applies only to medical devices intended for use in a clinical investigation within the meaning of section 2 of Annex X to Directive 93/42/EEC. The purpose of such a investigation must be: 1) to verify whether the performance of the medical device conforms to the medical performance specified by the manufacturer; 2) to determine any undesirable side-effects under normal conditions of use, and assess whether they constitute risks when weighed against the intended performance of the device.

- ✓ *Where a manufacturer supplies a medical device for the purpose of performing a clinical investigation within the meaning of section 2 of Annex X to Directive 93/42/EEC, the manufacturer must meet the obligations imposed by Dutch law in that respect. One of the requirements is that the manufacturer must notify the competent authority (Central Committee on Research Involving Human Subjects, CCMO) of the clinical investigation.*

It is prohibited for a manufacturer to supply a medical device without CE marking if the purpose of the clinical investigation is not as defined in section 2 of Annex X to Directive 93/42/EEC.

The law further prohibits use of a medical device by medical researchers if the medical device was not delivered in conformity with the relevant articles of the Medical Devices Decree (BMH). Consequently, the researcher has a duty to make sure that the manufacturer supplied the medical device in conformity with the law.

- ✓ *The Inspectorate maintains supervision over compliance with aforementioned legislation, and in some cases breaches of the legislation carry an immediate administrative fine. Both the manufacturer and the principal investigator may be fined.*
- ✓ *As a result of the legislation, Investigator-Initiated Investigation without involvement of the manufacturer is **not** possible with non-CE-marked medical devices or with medical devices whereby application of the device during the investigation is **not** for the same purpose as intended in the relevant conformance evaluation procedure. This means that a researcher cannot take the initiative to perform a clinical investigation for a new medical device or a new application of an existing medical device if the manufacturer is not involved to such an extent that it is able to meet all responsibilities assign to him by Dutch law.*

- ✓ *Many clinical investigations are subject to the Medical Research (Human Subjects) Act (WMO). This includes research involving medicines, operations, or medical devices. Research that falls under the Medical Research (Human Subjects) Act (WMO) must meet all requirements stated in the Act. In any case, the clinical investigation involving the use of medical devices discussed on this page is automatically covered by the Medical Devices Act (WMH) and is therefore required to meet the requirements contained therein. While clinical investigations with medical devices are often covered by the Medical Research (Human Subjects) Act (WMO), this is not always the case. If a clinical investigation is covered by it, it is necessary to satisfy the requirements contained in both Acts (WMO and WMH). If it is not covered by the Medical Research (Human Subjects) Act (WMO), it is still necessary to comply with the stipulations made in the Medical Devices Act (WMH).*

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