

Decree of the Council of State (Finland)

concerning *in vitro* diagnostic medical devices

Issued in Helsinki on September 29th, 2000
(Unofficial English translation)

Having regard to § 23 of the Medical Devices Decree (1506/94), passed on 29 December 1994, the Council of the State has decided the following:

§ 1.

European Community Act enforced by this decree

Directive 98/79/EC of the European Parliament and of the Council on *in vitro* diagnostic medical devices shall be enforced by this decree.

§ 2.

Scope

This decree shall apply to the essential requirements and conformity assessment procedures relating to *in vitro* diagnostic medical devices and their accessories.

In vitro diagnostic medical device means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens derived from the human body, solely or principally for the purpose of providing information:

- concerning a physiological or pathological state,
- concerning a congenital abnormality,
- to determine the safety and compatibility in connection with blood and tissue donations, or
- to monitor therapeutic measures.

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Calibrator and control materials refer to any substance, material or article intended by the manufacturer either to establish measurement relationships or to verify the performance characteristics of a device in connection with the intended use of the device.

Products for general laboratory use are not *in vitro* diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for *in vitro* diagnostic examination.

§ 3.

Specimen receptacles and devices

Specimen receptacle is a device, whether vacuum-type or not, specifically intended for the primary containment and preservation of specimens derived from the human body immediately following sampling for the purpose of *in vitro* diagnostic examination.

Invasive sampling device or other medical device referred to in the decision concerning medical devices issued on 29 December 1994 by the Ministry of Social Affairs and Health which is placed directly on the surface of the human body for sampling, shall not be considered to be accessory of an *in vitro* diagnostic medical device.

§ 4.

Essential requirements

The essential requirements concerning *in vitro* diagnostic medical devices are set out in Annex 1 of this decree.

§ 5.

Classification criteria

In vitro diagnostic medical devices are divided into two main product classes on the basis of how far their correct performance is essential for medical practice or the

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failure of which can cause a serious risk to health. Devices whose performance is subject to special requirements are set out in Annex 2 List A very sensitive devices and List B sensitive devices.

§ 6.

Very sensitive devices

For very sensitive devices set out in List A of Annex 2 of this decree other than those intended for performance evaluation, the manufacturer shall, for the purpose of affixing the CE marking

- follow the procedure relating to the EC declaration of conformity (full quality assurance system) set out in Annex 4 of this decree, or
- follow the procedure relating to the EC type-examination set out in Annex 5 of this decree coupled with the procedure concerning the EC declaration of conformity (production quality assurance) set out in Annex 7 of this decree.

§ 7.

Sensitive devices

For sensitive devices set out in List B of Annex 2 of this decree other than those intended for performance evaluation, the manufacturer shall, for the purpose of affixing the CE marking

1. follow the procedure concerning the EC declaration of conformity (full quality assurance system) set out in Annex 4 of this decree, or
2. follow the procedure concerning the EC type-examination set out in Annex 5 of this decree coupled with the procedure concerning EC verification set out in Annex 6 of this decree or the EC declaration of conformity (production quality assurance) set out in Annex 7 of this decree.

§ 8.

Devices for self-testing

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For self-testing devices other than sensitive and very sensitive devices referred to in Annex 2 and devices intended for performance evaluation, the manufacturer shall, for the purpose of affixing the CE marking

- follow the procedure set out in Annex 3 of this decree and meet the additional requirements set out in point 6 of Annex 3 and draw up an EC declaration of conformity, or
- follow the procedure concerning the EC declaration of conformity (full quality assurance) set out in Annex 4 of this decree, or
- follow the procedure concerning the EC type-examination set out in Annex 5 of this decree coupled with the procedure relating to EC verification set out in Annex 6 of this decree or the EC declaration of conformity (production quality assurance) set out in Annex 7 of this decree.

§ 9.

Devices intended for performance evaluation

For devices intended for performance evaluation the manufacturer shall follow the procedure set out in Annex 8 of this decree.

§ 10.

Other devices

For devices other than those referred to in § 6-9 of this decree the manufacturer shall follow the procedure set out in Annex 3 of this decree and draw up an EC declaration of conformity for the purpose of affixing the CE marking.

§ 11.

Power of authorized representatives

A manufacturer's authorized representative may carry out the procedures relating to the EC conformity declaration, EC type-examination, EC verification and confirmation of conformity in relation to devices intended for performance evaluation on behalf of the manufacturer.

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§ 12.

Inspections and assessments carried out by a notified body

Decisions taken by a notified body as set out in Annexes 3, 4 and 5 shall be valid for a maximum of five years. The validity of the decision may be extended for further periods of five years by written agreement between the parties.

Requirements concerning notified bodies are laid down in Annex 9 of this decree.

§ 13.

Miscellaneous provisions

This decree shall be applied as appropriate to a natural or legal person who manufactures *in vitro* diagnostic medical devices and puts them into service and uses them in his professional capacity without placing them on the market. However, this decree shall not be applied to manufacture of devices by health institutions referred to in point 6 of § 1 of the Council of State decree.

This decree shall not apply to instruments, apparatus, appliances, material or other articles including computer software intended for other than medical scientific use.

Where appropriate, the National Agency for Medicines shall give instructions concerning the application of this decree.

§ 14.

Coming into force

This decree will come into force on 7 June 2000.

A manufacturer or importer or other person responsible for placing *in vitro* diagnostic medical devices on the market or putting them into service may place devices referred to in this decree on the market until 7 December 2003, even if a device does not meet the requirements laid down in the Medical Devices Act as amended by the Act

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(791/92) of 21 August 1992. *In vitro* diagnostic medical devices meeting the requirements of the said Act may be put into service until 7 December 2005.

Minister at the Ministry of Social Affairs and Health *Osmo Soininvaara*

Ministerial Councillor *Pekka Järvinen*