

NORMATIVE GUIDELINE 3/2005
20th December.2005

NOTIFICATIONS OF MEDICAL DEVICES TO THE PRODUCT REGISTER

Legal basis

Sections 14, and 15 and section 30, subsection 5 of the Medical Devices Act

Section 7 of the Decree of the Ministry of Health and Social Affairs concerning notifications to be submitted on certain medical devices

Target groups

Manufacturers of medical devices

Assemblers of systems and procedure packs

Producers of sterilization services

Importers of in vitro diagnostic devices intended for self-testing, including certain devices considered to be risk-prone

Authorised representatives

Period of validity

1.1.2006 - 31.12.2009

Abrogated guidelines

Notification concerning domestic manufacturer 8/2001

Notifications concerning the placing of devices intended for in vitro diagnostics on the market and putting them into service 1/2000

CONTENTS

1. GENERAL	3
1.1 Product register	3
1.2 Scope.....	3
2. PRODUCTS SUBJECT TO NOTIFICATION	3
2.1 Medical devices in Class I	3
2.2 Medical devices in Class IIa, IIb and III, active implantable devices, and devices intended for in vitro diagnostics in accordance with appendix 2 of the IVD decree.....	4
2.3 Devices manufactured for individual use	4
2.4 Medical devices intended for in vitro diagnostics	4
2.5 Systems and procedure packs	4
2.6 Notification concerning sterilization services.....	5
2.7 Devices considered particularly risk-prone	5
2.8 Devices containing human tissue or substances originating from human blood or blood plasma	6
3. SUBMISSION OF INFORMATION	6
3.1 Persons subject to the notification obligation	6
3.2 Content of notifications.....	6
3.3 Deadlines for submitting notifications.....	7
4. COMING INTO FORCE.....	7
 APPENDIX 1 Definitions	 9

1. GENERAL

1.1 Product register

The National Agency for Medicines maintains a product register containing information on Finnish manufacturers of medical devices, the products manufactured by them, the authorised representatives established in Finland, and the importers of in vitro diagnostic devices intended for self testing. Finnish manufacturers and authorised representatives are required to provide the product register with the necessary information. Notification must be made to the product register of devices that contain human tissue or substances originating from human blood or blood plasma. The product register does not contain information on the manufacturer of devices by health care units themselves when such devices are manufactured solely for use by the unit in question.

Maintenance of the product register is based on section 15 of the Medical Devices Act. Failure to notify is punishable under section 24 of the Medical Devices Act.

1.2 Scope

This guideline applies to products that are placed on the market and put into service in accordance with the legislation on medical devices:

- The Medical Devices Act (1505/1994)
- The Medical Devices Decree (1506/1994)
- The Decree on in-vitro diagnostic medical devices (830/2000, hereinafter the IVD decree)
- The Decision of the Ministry of Social Affairs and Health on medical devices (1994:66)
- The Decision of the Ministry of Social Affairs and Health on active implanted devices (1994:67)

The National Agency for Medicines issues the following guidelines on the procedures according to which a manufacturer of medical devices, an authorised representative, or other person subject to the notification obligation is to provide the National Agency for Medicines with the necessary information.

2. PRODUCTS SUBJECT TO NOTIFICATION

2.1 Medical devices in Class I

Medical devices¹ are classified into four classes on the basis of the risk related to them. The smallest risk² is related to the devices of Class I. Devices belonging to Class I are those for which the manufacturer has designated a purpose that falls within Class I. The use of the device must be apparent, for example, from the technical documents related to the product, the demonstration material, and the advertising material. To demonstrate conformity with the requirements, the manufacturer may rely on either tests or evaluation procedures conducted by him or acquire the services he needs from a competent test laboratory.

Devices of Class I that are to be placed on the market sterile and that perform a measurement function also require notification to the product register despite the fact that the manufacturer must use a

¹ Medical devices are defined in appendix 1.

² More detailed regulations on product classification and classification criteria are in Decision 1994/66 of the Ministry of Social Affairs and Health.

notified body to verify both sterility and the metrological requirements.

If a device, including its design and manufacture, meets the essential requirements concerning it, the technical documents concerning the product are appropriate, and the manufacturer has arranged a procedure for processing of information on the product obtained after production, the manufacturer must provide the product with the CE marking when placing it on the market.

2.2 Medical devices in Class IIa, IIb and III, active implantable devices,³ and devices intended for in vitro diagnostics in accordance with appendix 2 of the IVD decree

The National Agency for Medicines will henceforth issue its own guideline regarding the notification procedure and the information to be provided for medical devices in product class IIa, IIb, and III, active implantable devices, and devices intended for in vitro diagnostics in accordance with appendix 2 of the IVD decree.

2.3 Devices manufactured for individual use

Notification concerning devices manufactured in accordance with the written declaration of a medical expert for a designated individual patient (custom-made devices) must be made to the product register, despite the fact that the product may belong to different classes depending on its purpose and materials. Devices manufactured by continuous or serial production methods, which are modified for the special needs of a physician or other professional user, are not considered devices⁴ manufactured for individual use.

If a device, including its design and manufacture, meets the essential requirements concerning it, the technical documents of the product are appropriate, and the manufacturer has arranged a procedure for processing of information on the product obtained after production, the product can be put into service.

Devices manufactured for individual use cannot be provided with the CE marking. Instead, they should be provided with the text “device manufactured for individual use”.

2.4 Medical devices intended for in vitro diagnostics

Notification concerning all medical devices (hereinafter IVD devices) intended for in vitro diagnostics must be made to the product register. Notification concerning devices intended for performance evaluation must be made when the performance evaluation is made with a view to attachment of the CE marking.

If an IVD device, including its design and manufacture, meets the essential requirements concerning it, the technical documents of the product are appropriate, and the manufacturer has arranged a procedure for processing of information on the product obtained after production, the manufacturer must provide the product with the CE marking when placing it on the market. The CE marking is not attached to a device intended for performance evaluation.

2.5 Systems and procedure packs

Notification concerning systems and procedure packs⁵ comprising medical devices provided with

³ Active devices are defined in appendix 1

⁴ Devices manufactured for individual use are defined in appendix 1.

⁵ Systems and procedure packs are defined in appendix 1.

the CE marking in accordance with their purpose must be made to the product register, despite the fact that they may belong to different product classes on the basis of their purpose and materials.

If an assembler of a system and procedure pack has prepared a declaration verifying that he has ascertained the conformity of the products in accordance with the instructions of the manufacturer and reassembly was otherwise implemented in conformance with section 10 of the Decision of the Ministry of Social Affairs and Health (1944:66), he may place the system and procedure pack on the market.

The assembler of a system referred to above may not attach the CE marking to the product.

2.6 Notification concerning sterilization services

Notification concerning production of sterilization services⁶ must be made to the product register. Notification is made by anyone sterilizing systems or a procedure packs or other medical devices bearing the CE marking for their manufacturer, with a view to placing the products on the market.

The evaluation procedure for conformity and participation of a notified body apply to the sterility of the medical device and to the achievement of that sterility.

Producers of sterilization services must observe the evaluation procedures of their choice presented in the Decision of the Ministry of Social Affairs and Health (1994:66). A declaration stating that sterilization took place in accordance with the manufacturer's instructions must be prepared.

Producers of sterilization services may not attach the CE marking to a system, procedure pack, or other medical device sterilized by him.

2.7 Devices considered particularly risk-prone

The expanded notification obligation set out in the Decree of the Ministry of Social Affairs and Health on notifications to be submitted on certain medical devices (831/2000) applies to those medical devices that may pose a significant risk to health. Notifications must be made when the device is placed on the market or put into service.

Notification must be submitted concerning

- orthopaedic implants
- implants used in the treatment of fractures of the upper femoral bone and the spinal column
- dental implants
- surrogates for connective tissue and tendons
- vascular implants
- implants and their components used in obesity treatment
- medical laser devices, and
- IVD devices used for self testing.

Although notification concerning devices intended for self testing can be made with the same form as other register notifications for diagnostic medical devices (see subsection 3), information on symbols and instruction for use of the device must be appended to the notification. However, notification

⁶ Proper sterilization in the course of maintenance of non-disposable products that are either in use or to be placed in service is not regarded as the production of sterilization services.

concerning an IVD device intended for self testing need not be made if a corresponding device has been placed on the Finnish market and notification has been duly made, or if the device in question does not differ significantly from one for which notification has already been made.

The National Agency for Medicines will henceforth issue its own guideline on the more detailed content of notifications concerning the products mentioned above.

2.8 Devices containing human tissue or substances originating from human blood or blood plasma.

Manufacturers and importers of devices containing substances of human origin are required to submit notifications to the product register. The National Agency for Medicines will henceforth issue its own guideline on the more detailed content of the notifications.

3. SUBMISSION OF INFORMATION

3.1 Persons subject to the notification obligation

Manufacturers established in Finland must submit a notification to the product register if they

- 1) place medical devices on the market in their own name,
- 2) assemble systems and procedure packs to form a medical device, or
- 3) sterilize systems, procedure packs or medical devices bearing the CE marking

Authorised representatives established in Finland are required to submit similar notifications.

Importers are subject to the notification obligation only for IVD devices intended for self-testing or for devices that contain substances of human origin.

Those submitting notifications must be

- authorised to represent a company or business,
- the authorised representative of a manufacturer, or
- another person responsible for placing a medical device on the market.

3.2 Content of notifications

The National Agency for Medicines must be provided with all information concerning manufacturers, authorised representatives, and products, and with all information concerning the importers of IVD devices intended for self-testing and of devices containing substances of human origin.

Notifications regarding the manufacture of medical devices and of in vitro diagnostic devices and the import of certain devices must be made using the form designated for this purpose. Separate notification must be made for each device. Notification must be submitted whenever there are changes in the information already provided. The forms contain detailed instructions for completion.

Descriptions of devices must include their purpose and main features (for example, source of power, special restrictions on use, and when necessary the class).

3.3 Deadlines for submitting notifications

Notifications must be made within two weeks after a medical device, system, procedure pack or sterilization service has met the essential requirements stipulated in the Medical Devices Act, the conformity procedures for them have been carried out in accordance with what is stipulated in the rules and regulations, and the device has been placed on the market, or when the device has been submitted for performance evaluation.

Notifications concerning imports of a device intended for self-testing must be made within two weeks of initiation of imports.

The information referred to in this guideline must be submitted to the following address:

National Agency for Medicines
Medical Devices
Product Register
POB 55
FI-00301 Helsinki
FINLAND

Forms intended for making notifications in accordance with this guideline are available on the National Agency for Medicine website (www.nam.fi/publications/forms). Forms can also be ordered from the address mentioned above, by e-mail (laiterekisteri@nam.fi), or by telephone at +358 9 473 341. The National Agency for Medicine updates forms when necessary.

The National Agency for Medicines sends an extract from the register based on the notification to the person submitting it.

For additional information regarding the notification procedure, inquire at the National Agency for Medicines by telephone at +358 9 473 341 or by e-mail (laiterekisteri@nam.fi).

4. COMING INTO FORCE

This guideline will come into force on 1st January 2006 and will remain in force until 31st December 2009.

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Finnish Union of Practical Nurses
Finnish Medical Association
Finnish Nurses Association
Association of Ophthalmic Opticians in Finland
Union of Health and Social Care Professionals
Finnish Health Care Technology Association

APPENDIX 1 Definitions

Medical device refers to an instrument, equipment, apparatus, material, or other device, whether used alone or in combination, including the software necessary for its proper function, intended by the manufacturer to be used in relation to human beings for the purpose of

- a) diagnosis, prevention, monitoring, treatment or alleviation of disease,
- b) diagnosis, monitoring, treatment, alleviations of or compensation for an injury or disability,
- c) investigation, replacement or modification of the anatomy or of a physiological process, or
- d) control of conception.

The functioning of a device may be assisted through pharmacological, immunological, or metabolic means, provided that its principal intended effect is not achieved by such means.

Active implantable device refers to a medical device operated by electricity or power other than that generated directly by the human body or gravity and which is intended either to be implanted permanently, either as a whole or in part, in the human body by a surgical or other medical method or by means of a medical procedure in a natural orifice of the human body, and which is intended to remain in place after the procedure.

Device manufactured for individual use (custom-made device) refers to a device manufactured in accordance with the written declaration of a medical expert for an individual designated patient. Detailed design instructions for the device are provided in a declaration at the responsibility of the expert. A device manufactured by a continuous or serial production method that is modified for the special needs of a physician or other professional user is not regarded as a device manufactured for individual use.

In vitro diagnostic medical device refers to a medical device that is a reagent, reagent product, calibrator, control material, test kit, instrument, device, apparatus or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens taken from the human body solely or principally for the purpose of obtaining data

- a) concerning a physiological or pathological state;
- b) concerning a congenital abnormality;
- c) to determine safety or compatibility in conjunction with blood and tissue donations; or
- d) to monitor therapeutic measures.

Device intended for self-testing refers to a medical device intended for in vitro diagnostics which the manufacturer has intended for use at home by other than professional medical personnel.

Device intended for performance evaluation refers to a medical device intended for in vitro diagnostics intended by the manufacturer for performance evaluation of one or more devices in a clinical laboratory or other facility outside the premises of the manufacturer.

Manufacturer refers to a natural or legal person who places a medical device on the market in his own name. A natural or legal person, who assembles, packages, processes, fully refurbishes, or labels one or more products or assigns to them their intended purpose as a medical device with a view to being placed on the market under his own name is regarded as a manufacturer.

The name of the manufacturer or firm and address must be stated in the markings for the medical device.

Authorised representative refers to a natural or legal person established in the area of the European Community, who, explicitly designated by the manufacturer, acts on behalf of the manufacturer and may be addressed by the authorities and bodies instead of the manufacturer with regard to the latter's obligations in the regulations issued in the Medical Devices Act and thereunder.

Placing on the market refers to the first placing in service of a medical device against payment or free of charge, with a view to distribution or use in the area of the European Community, regardless of whether it is new or fully refurbished. Use of the device for clinical research or for performance evaluation investigation of a medical device is not regarded as placing on the market.

If the manufacturer is not established in the Member States (with respect to an IVD device), the manufacturer must designate an authorised representative. The authorised representative is responsible for submitting the register notification to a competent official of the Member State in which the domicile of the representative is located.

Products are regarded as a system and procedure pack if

- a) all the individual medical devices contained in the system or procedure pack have been provided by the manufacturer with the CE marking, and
- b) the assembler of the system and procedure pack uses individual medical devices in accordance with their purpose and within the restrictions set by the manufacturer with a view to placing the product on the market

