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Finnish Medicines Agency Administrative Regulation

Operator and device register notifications related to medical devices to the authorities

Lääkealan turvallisuus- ja kehittämiskeskus | Säkerhets- och utvecklingscentret för läkemedelsområdet | Finnish Medicines Agency
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Legal basis

Medical Devices Act (719/2021), section 49, subsection 12.

Target groups

Manufacturers of medical devices, authorised representatives, importers and system or procedure pack assemblers as well as providers of sterilisation services, health care units engaged in in-house device manufacturing, and distributors of medical devices.

Additionally, operators who make available on the market an in vitro diagnostic (IVD) device for self-testing or a medical device containing human tissue or substances derived from human blood or plasma, which they have imported to Finland.

This Administrative Regulation shall not apply to devices and accessories intended for clinical device trials or to IVD devices intended for performance evaluations.

Entry into force

This Administrative Regulation will enter into force on 17 August 2021 and will remain so until further notice.

Regulation repealed

Regulation 2/2010 of the National Supervisory Authority for Welfare and Health on device register notifications concerning medical devices and supplies.

This regulation implements

Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (32017R0745); OJEU L 115, 5 May 2017, p. 1

Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices and repealing Directive 98/79/EC

and Commission Decision 2010/227/EU (32017R0746); OJEU L 117, 5 May 2017, p. 176

Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices (31998L0079); OJEU L 331, 7 December 1998, p. 1

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1 General

This Administrative Regulation of the Finnish Medicines Agency (Fimea) lays down more detailed provisions on the information content of the operator and device notifications pursuant to the legislation concerning medical devices and on the applicable notification procedures.

1.1 Scope of application

This Administrative Regulation applies to the economic operators referred to in the regulations concerning medical devices, (EU) 2017/745 (MDR) and (EU) 2017/746 (IVDR), who operate in the field of medical devices, as well as to the operators liable to file a notification under the Act on Medical Devices (719/2021).

1.2 Definitions

For the purposes of this regulation, the following terms shall have the following meanings:

Eudamed means the European database on medical devices;

SRN means the operator-specific single registration number assigned from the European database on medical devices;

UDI means the unique device identifier;

UDI-DI means the unique manufacturer and device-specific device identifier;

Fimea's reference number for supplier means the supplier-specific reference number assigned from Fimea's device register, which the supplier will later use when registering data;

Fimea's reference number for device group means the device group specific reference number assigned from Fimea's device register, which the supplier will later use when registering devices;

Placing on the market[1] means the first making available of a device, other than an investigational device, on the Union market;

Making available on the market[2] means any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

Device group means a set of devices having the same or similar intended purposes or a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;

Device identification means the UDI-DI identifier or other identifier, such as the manufacturer's product or reference number, which allows the device to be uniquely identified;

Sterilisation service provider means the provider of sterilisation services referred to in section 16 of Act 629/2010 and the provider of sterilisation services referred to in Article 22(3) of the MD Regulation.

2 Operator and device notifications

Before placing medical devices on the market or making them available on the market, the operator shall file a notification with Fimea of its operations and devices. The registration of medical devices shall be carried out in two stages as described in this Administrative Regulation. First, the operator shall register either in the Eudamed database or in Fimea's device register, depending on the operator's role. The requirements for the operator's registration are described in section 2.1. After registration, the supplier will receive an SRN from the Eudamed database or a reference number for supplier assigned by Fimea, which the supplier shall use when registering devices. In the second step, the supplier shall register its medical devices related to operations in accordance with section 2.2.

The notification forms available on the Fimea website (www.fimea.fi) shall be used for notifying data. The forms are only published on the Fimea website

[1] See also Official Journal of the European Union 2016/C 272/01 Commission Notice – The 'Blue Guide' on the implementation of EU products rules 2016, section 2.3
[2] See also Official Journal of the European Union 2016/C 272/01 Commission Notice – The 'Blue Guide' on the implementation of EU products rules 2016, section 2.2

and contain the mandatory information that is to be declared in the notifications.

2.1 Registration of operators

The operator is liable to file a notification of its operations in the manner described in this Administrative Regulation. All the information defined as mandatory shall be declared in the notification. The operator's data, including business identity code, shall be stated in the format recorded in the Business Information System. A notification shall be filed separately for each of the operator’s roles and for each trade name. The individual filing the notification shall be an authorised representative of the company or trader.

2.1.1 Registration of economic operators

The following economic operators established in Finland referred to in the regulations on medical devices shall register in the Eudamed database maintained by the European Commission:

- a manufacturer or importer that places medical devices on the market in the European Economic Area;
- an authorised representative;
- a system or procedure pack assembler, or steriliser thereof; and
- the manufacturer of a custom-made device, if a notified body has been used in the conformity assessment of the device.

The economic operator shall state all the information defined as mandatory in the Eudamed database.

2.1.2 Operators liable to file a notification under the Medical Devices Act

Operators liable to file a notification under section 49 of the Medical Devices Act also include the following:

- manufacturer, authorised representative and importer of devices pursuant to the In-Vitro Diagnostic Devices Directive 98/79/EC;
- manufacturer of custom-made devices, excluding manufacturers of risk class III implantable devices (see section 2.1.1);
- health care unit engaged in device manufacturing;

- sterilisation service provider that sterilises CE-marked medical devices pursuant to the directives before they are put into service. Units that carry out in-house instrument maintenance at a healthcare unit are not liable to file a notification. However, if such a unit offers its sterilisation services to a manufacturer that places the final product on the market, the service provider concerned shall file a notification with Fimea;
- those distributing medical devices to retailers and professional users; and
- those who make available on the market an IVD device for self-testing or a medical device containing human tissue or substances derived from human blood or plasma, which they have imported to Finland.

The notification forms available on the Fimea website (www.fimea.fi) shall be used for notifying data. The forms are only published on the Fimea website and contain the mandatory information that is to be declared in the notifications.

After the deployment of Fimea's electronic submission service, the operator shall check all of its data and update it where necessary via the e-submission service within 60 days at the latest.

Fimea will notify the registered operators when the e-submission service is put into service.

2.2 Registration of devices

The operator specified in section 2.1.1 shall, before placing on the market the medical device manufactured, imported, represented or sterilised by the same, notify the information specified in section 2.2.1 to Fimea and later to the Eudamed database when its device section is ready. The manufacturer or importer specified in section 2.1.2 shall, before placing the device on the market, notify the device-related data specified in section 2.2.2 to Fimea as applicable. The other operators specified in section 2.1.2 shall notify the equivalent data related to the devices they have made available on the market. The notification forms available on the Fimea website (www.fimea.fi) shall be used for notifying data. The forms are only published on the Fimea website and contain the mandatory information that is to be declared in the notifications.

2.2.1 Registration of the devices of operators referred to in the regulations on medical devices

The manufacturer or authorised representative shall submit to Fimea the device group data required by Fimea on devices pursuant to the medical device regulations (EU) 2017/745 and (EU) 2017/746 until the device section of the Eudamed database has been place into service. Additionally, with regard to devices that belong to a device group, the manufacturer or authorised representative shall state their UDI-DI, the manufacturer's name and the trade name. For devices pursuant to Directives 90/385/EEC and 93/42/EEC and Regulation (EU) 2017/745 imported to the European Economic Area, the importer shall declare the identification, trade name, manufacturer and authorised representative of the device. The importer shall declare the import of devices pursuant to Directive 98/79/EC and Regulation (EU) 2017/746 as of the date of application of the IVD Regulation. The notification forms available on the Fimea website (www.fimea.fi) shall be used for notifying data. The forms are only published on the Fimea website and contain the mandatory information that is to be declared in the notifications.

A system or procedure pack assembler shall state the devices contained in the system or procedure pack and their intended use as well as the information based on which they can be identified. An operator sterilising systems or procedure packs shall state the information concerning the devices to be sterilised and the sterilisation methods used.

The afore described device information notified using Fimea's forms shall be recorded in the Eudamed database no later than within 60 days of the date when the device section of the Eudamed database had been put into service. When recording the data, it shall be supplemented with regard to any mandatory data required by the Eudamed database.

Fimea will notify the registered operators when the Eudamed database is put into service.

2.2.2 Registration of certain devices other than those of operators referred to in the regulations on medical devices

The operator shall state the device group data required by Fimea concerning devices pursuant to medical device directives 90/385/EEC, 93/42/EEC and 98/79/EC. In addition, the operator shall state the devices, their risk class, intended purpose, operating principle and any information based on which the device can be identified. The notification forms available on the Fimea website (www.fimea.fi) shall be used for notifying data. The forms are only published on the Fimea website and contain the mandatory information that is to be declared in the notifications.

A sterilisation service provider shall provide information on the sterilisation methods used.

The aforementioned device data declared using Fimea's forms must be checked and completed no later than 60 days of the date when Fimea's electronic submissions for medical devices have been place into service. When checking the data, it shall be complemented with regard to the mandatory information required for Fimea's e-submission service.

Fimea will notify the registered operators when the e-submission service is put into service.

2.2.3 Distributor's notification of devices made available

An operator distributing devices to retailers, healthcare and social welfare operators and other professional users that makes equipment available on the market in Finland shall file a notification of its operations with Fimea. The operator shall also submit a list of the devices it distributes on an annual basis, including the following information: identification, manufacturer, item name and trade name of the device. Furthermore, the regulation under which the device has been placed on the market shall be indicated for each device. The notification forms available on the Fimea website (www.fimea.fi) shall be used for notifying data. The forms are only published on the Fimea website and contain the mandatory information that is to be declared in the notifications.

2.3 Keeping registration data up to date

The operators liable to file a notification shall keep up to date the data they have declared to the Finnish Medicines Agency. Any material changes to the registered data shall be notified to Fimea without delay.

3 Guidance and advice

On request, the Finnish Medicines Agency Fimea will offer guidance and advice on the application of this Administrative Regulation.

Note:

In section 2.1.1, medical devices refer to medical devices that are regulated both under directives and regulations.

4 Entry into force

This Administrative Regulation will enter into force on 17 August 2021 and will remain so until further notice.

Director General Eija Pelkonen

Senior Inspector Jari Knuuttila

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