Guidelines for distributors of medical devices

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1 Version management

Version number	Date of publication	Changes
1.0	December 12th, 2022	New guideline published
2.0	June 16th, 2025	Updated online links

2 Purpose of the guideline

The legislation on medical devices has undergone a significant change with the update of relevant EU regulations and national laws. The revised legislation set obligations for distributors of medical devices.

With this guideline, the Finnish Medicines Agency Fimea provides distributors with information on requirements for medical devices and how to implement them in practice. The practical implementation is illustrated with examples.

In this guideline, a medical device refers to medical devices as defined in the Regulation on medical devices (MDR, EU 2017/745) and in the Regulation on in vitro diagnostic medical devices (IVDR, EU 2047/746).

NOTE! EVERY DISTRIBUTOR IS ALWAYS OBLIGATED TO GET ACQUAINTED WITH THE REGULATIONS GOVERNING THEIR OPERATIONS.

Further information:

- Fimea website - Legislation related to medical devices

3 How to use this guideline

This guideline includes several links you can use to move to a topic of interest within this document. The most practical way to see the links is through the Bookmarks menu of the PDF reader. Some of the links lead to external sources of information, such as websites that contain information on the topic in question. Because of the links, it is most convenient to read this guideline in electronic format.

At the bottom of the pages, there is a content band which shows the topics of the guideline on the title level. As you read the guideline, the title of the currently displayed page/topic is highlighted in the content band.

This guideline also contains a Q&A section with a collection of questions presented to Fimea on the requirements for distributors.

The symbols from SFS EN ISO 15223-1 have been published with the permission of the Finnish Standard Association SFS.

4 What is a medical device?

For example, devices used in hospitals, implants and instruments as well as thermometers and plasters found in every household are easy to conceive as medical devices. However, it can be more difficult to identify applications, contraceptives, assistive devices, textiles, solutions or ointments, etc. as a medical device. Whether a product is a medical device or not depends on the intended purpose specified by the manufacturer.

It is the manufacturer's responsibility to consider if the product fulfils the definition of a medical device. If it does, the manufacturer must indicate this using appropriate labels (see also section Labels). However, it is useful for distributors to be aware of the definition of a medical device.

These examples are medical devices:

- Wound care products
- Heart rate monitors indicated for the identification of heart diseases
- Bright light lamps used for the treatment of seasonal affective disorder
- Pregnancy and ovulation tests
- Surgical face masks
- Disinfectants for damaged skin
- Eyeglasses to improve impaired vision
- Condoms

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These examples are not medical devices

- Hygiene products
- Heart rate monitors only used for monitoring your fitness level
- Personal protective equipment (e.g. FFP masks)
- Hand sanitisers
- Gene tests used for genealogy
- Dosette boxes

Further information:

- Definition of medical devices: MDR Article 2(1)
- Definition of in vitro devices: IVDR Article 2(2)

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5 Am I a distributor or an importer?

A distributor **makes a device available on the market** but is not a manufacturer or importer.

An importer is established in the European Union and **places a device from a third country on the EU market**. For this purpose, the European Union is seen as a single country. For example, a Finnish company which imports devices to the Union market from a manufacturer located in Asia or Northern America is considered an importer.

One operator can have only one role per a certain device under the Regulation. In other words, it is possible for a person or a company to be an importer of some devices and a distributor of others, but one person or company cannot be both an importer and a distributor of the same device under MDR or IVDR.

It is essential to define the role to identify the applicable requirements. Importers and distributors have their own general obligations.

Terms:

- Placing a device on the market
  - What: Making a device available on the Union market for the first time
  - Who: Manufacturers and importers

- Making a device available on the market
  - What: Distributing and selling a device imported in the EU
  - Who: Distributors

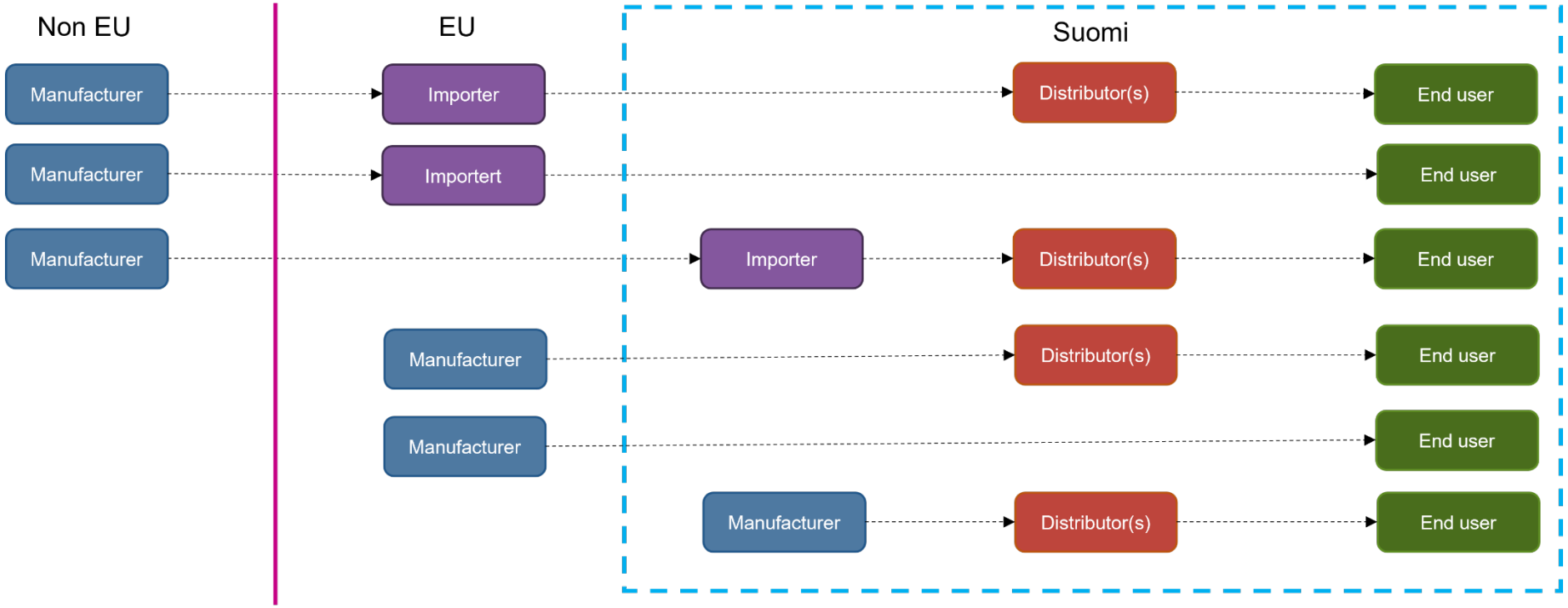

Figure 1 Examples of the relationships between manufacturers, importers and distributors in the supply chain of a device.

As depicted in Figure 1, an operator established in Finland may be a manufacturer, importer or distributor of a device. If the manufacturer of the device is established outside the EU (e.g. in Northern America) and there are no other operators between the manufacturer and the Finnish operator, the Finnish operator is considered to be the importer. However, if the manufacturer is established in an EU Member State (e.g. France), the Finnish operator is considered to be a distributor. A manufacturer and importer may also distribute devices themselves to end users.

A manufacturer can operate in several countries and both in and outside the EU. The manufacturer of a device that complies with the Regulation is marked on the EU declaration of conformity and the device/package/ instructions for use. An operator is interpreted to be an importer or distributor based on the information of a manufacturer that complies with the Regulation and not the physical place of manufacture, for example.

Further information:

- Definition of importer, MDR Article 2(33), IVDR Article 2(26)
- General obligations of importers, MDR Article 13, IVDR Article 13
- Definition of distributor, MDR Article 2(34), IVDR Article 2(27)
- MDCG guidance on the implementation of Articles 13 and 14: MDCG 2021-27 Rev. 1

6 Am I a distributor liable to file a notification?

Distributors are liable to file a notification to Fimea if

- they make a medical device available on the Finnish market to retailers, healthcare and social welfare operators and other professional users; or
- they make available on the Finnish market an IVD intended for self-testing or a medical device that contains human tissue or a human blood or plasma derivative they have imported to Finland

Please note that you cannot be a distributor liable to file a notification, importer and manufacturer for the same device. For example, a manufacturer does not file a distributor notification for a device it distributes itself. (See Figure 1)

A distributor liable to file a notification must register as an operator in Fimea's CERE register. In 2025, the supervision fee for distributors liable to file a notification is EUR 500.

Further information:

- Fimea website: Registrations

7 General obligations of distributors

Before distributing a device

1. Check the labels, instructions for use and the EU declaration of conformity
2. Inform of non-conformities
3. Store and transport the device in accordance with the manufacturer's requirements

After distributing a device

4. Inform of non-conformities
5. Inform of suspected incidents
6. Keep a register of complaints, non-conforming devices and of recalls and withdrawals
7. Co-operate with authorities

Further information:

- General obligations of distributors, MDR Article 14, IVDR Article 14

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7.1 Check the labels, instructions for use and the EU declaration of conformity

Before the distribution of a device, distributors must check that

1. The device has been CE marked and the manufacturer has drawn up the EU declaration of conformity of the device;
2. The manufacturer has labelled the device in accordance with the Regulation and the device is accompanied by the required instructions for use which meet the local language requirements;
3. Where applicable, information about the importer and the Unique Device Identifier (UDI) have been applied appropriately.

7.1.1 Labelling

The manufacturer must draw up identification information for the device and the manufacturer and submit all necessary information on the safe use of the device.

The device and the intended purpose define what information is necessary. If you suspect that the information and/or labels are incomplete, notify operators and, when necessary, Fimea.

Necessary information can appear on the device itself, the package or the instructions for use.

Symbols can be used for providing information.

NOTE! The distributor must check that the importer has not covered up the information provided by the manufacturer with their own labels.

Examples of symbols

- CE marking
- MD and IVD symbols
- Symbols related to the supply chain
- Device symbols
- Unique Device Identifier (UDI)
- Examples of packages and labels

Further information:

- Requirements regarding the information supplied with the device, MDR Annex I, Chapter III, IVDR Annex I, Chapter III

CE marking

With the CE marking, the manufacturer declares that a medical device complies with the requirements set out in EU Regulations.

The CE marking on the device/package must be visible, readily identifiable and permanent.

Figure 2. CE marking

For some medical devices, a notified body must perform a conformity assessment. In this case, the CE marking must be accompanied by the 4-digit identification number of the notified body. The identification number must be next to the CE marking.

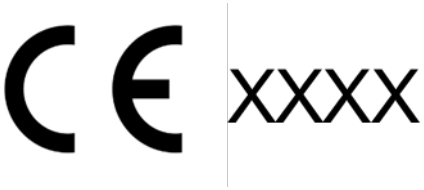

Figure 3. CE marking followed by the 4-digit identification number of the notified body

MD and IVD symbols

Devices under MDR must bear a MD symbol or information stating that it is a medical device.

Figure 4. Symbol of medical devices (MD), see SFS EN ISO 15223-1.

Devices under IVDR must bear an IVD symbol or information stating that it is an in vitro diagnostic medical device. Home tests must also indicate that it is a device intended for self-testing.

Figure 5. Symbol of in vitro diagnostic (IVD) medical devices, see SFS EN ISO 15223-1.

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Symbols related to the supply chain

Table 1. Examples of symbols related to the supply chain Information about the authorised representative and importer is required if the manufacturer of the device is not established in an EU Member State.

Symbol (SFS EN ISO 15223-1)	**Meaning**	**Indicated information**
	Manufacturer	Name and address of manufacturer
	Authorised representative	Name and address of authorised representative
	Importer	Name and address of importer
	Distributor	Name and address of distributor

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Device symbols

Table 2. Examples of device symbols

Symbol (SFS EN ISO 15223-1)	Meaning	Indicated information
	Use by	Clearly indicates the date after which the device is not to be used.
	Date of manufacture	Where there is no indication of the date until when it may be used safely.
	Manufacturer's batch number	Identifies the batch. A batch number is necessary when the product has not been identified with a serial number.
	Manufacturer's serial number	Identifies the device

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Unique Device Identifier (UDI)

UDI is a unique numeric or alphanumeric code specific to a medical device. It allows for unequivocal identification of devices on the market and facilitates their traceability.

The UDI comprises the following components:

- a device identifier (UDI-DI)
- a production identifier (UDI-PI)

The UDI can be provided in machine-readable format (e.g. a barcode) and also in human-readable format, when necessary.

NOTE! Devices under the Regulation need to have an UDI. However, there is a transitional period based on the devices' risk class **for placing the UDI on the device or the packaging**.

Further information:

- Commission website: Unique Device Identifier (UDI)
- EU UDI Helpdesk: Transitional periods for UDI
- MDCG guidance on UDI: MDCG 2022-7
- Unique Device Identification system: MDR Article 27, IVDR Article 24

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Examples (1/3) – a single-packaged syringe

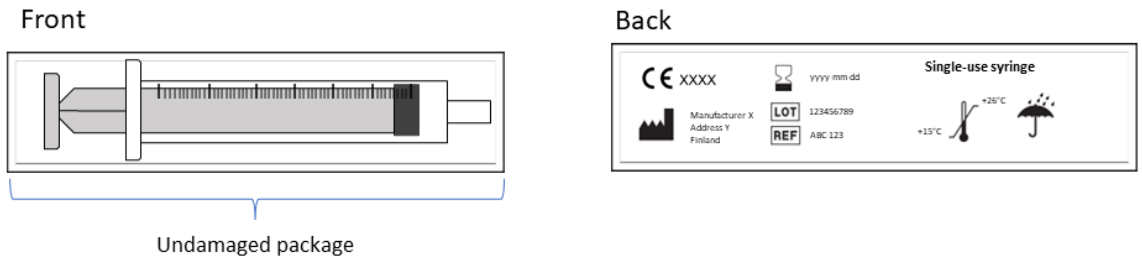

Figure 6 An example of a package of a single-packaged syringe

What do the package labels mean?

- The device is a single-use syringe that has been assessed by a notified body
- Its manufacturer is established in the EU, meaning that an authorised representative or an importer is not required
- The syringe has been assigned a batch number for traceability and identification
- The device has a use by date
- The manufacturer has defined certain storage conditions the distributor must adhere to during the time it is responsible for the device: the storage temperature for the device is +15°C…+26°C, and the package must be protected against humidity.

When can I distribute a device as single-packaged?

Primarily, a device should be distributed in the package size indicated by the manufacturer. It is possible to change the package size, however, provided that the distributor meets the requirements set out in the Regulations (see the Q&A section for more information).

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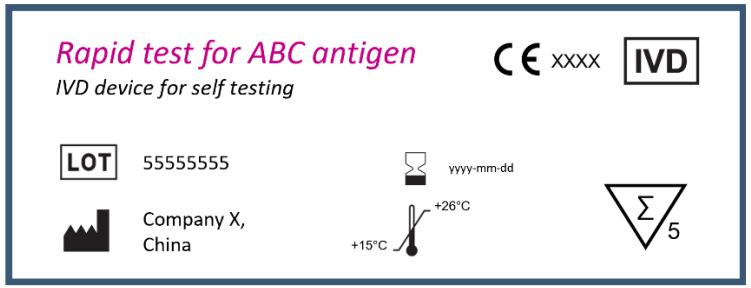
Examples (1/3) – an at-home rapid test

Front



Back

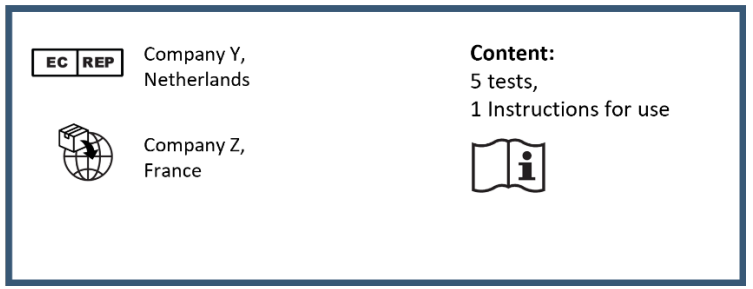


Figure 7 An example of a package of an at-home rapid test

What do the package labels mean?

- The device is an IVD indicated for self-testing;
- The device has been assessed by a notified body;
- The manufacturer is not established in one of the EU Member States;
- In this example, the package shows information about both the authorised representative and the importer;
- The test has been assigned a batch number for traceability and identification;
- The package includes instructions for use you must read before use;
- The device has a use by date;
- The package contains a total of 5 tests (∑);
- The manufacturer has defined certain storage conditions the distributor must adhere to during the time it is responsible for the device: the storage temperature for the device is +15°C...+26°C.

Examples (3/3) – a procedure pack

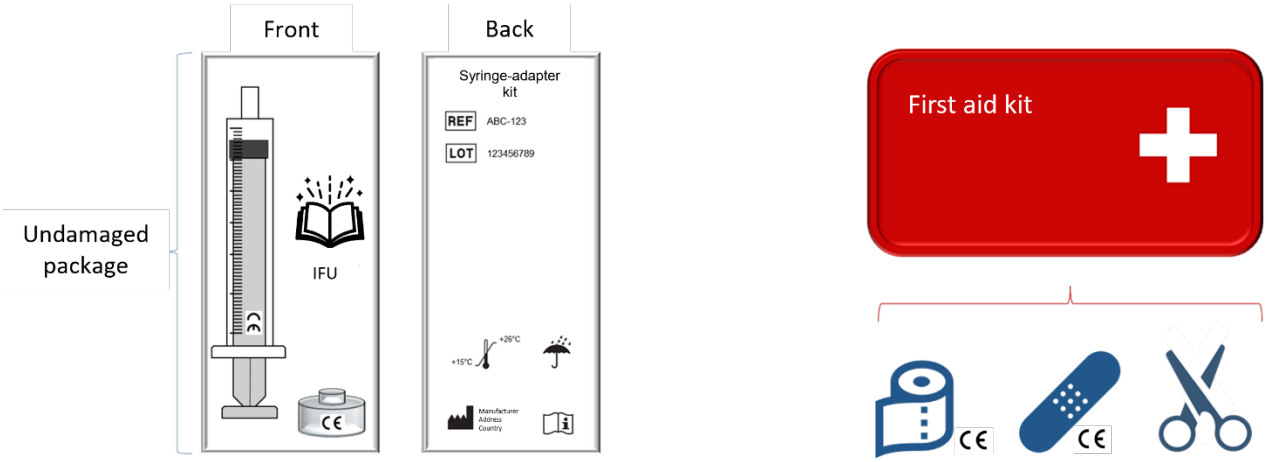


Figure 8 Two examples of a procedure pack: a syringe-adapter kit and a first-aid kit

A procedure pack refers to a combination of products provided in a single package and intended for medical use. The syringe-adapter kit and first-aid kit depicted in the image are examples of a procedure kit. Procedure packs **cannot themselves bear a CE marking**. Instead, the medical devices included in the package must bear the CE marking. The package can include other products as well, provided that their presence is otherwise justified (e.g the scissors in Figure 8 intended for cutting the bandage roll included in the first-aid kit).

Further information:

- Systems and procedure packs MDR Article 22

7.1.2 Instructions for use

The manufacture must supply instructions for use with the device, unless it is a device that is safe to use without instructions. The manufacturer may also provide the instructions for use in electronic format if the manufacturer and the device meet the requirements for electronic instructions for use. As a result, instructions for use are not always supplied with a medical device. If the use of a device requires the user to read the instructions for use, the manufacturer indicates this with the Consult instructions for use symbol (Figure 9).

Figure 9 Consult instructions for use symbol, see SFS EN ISO 15223-1.

If you suspect that a device should be accompanied with instructions for use or the provided instructions for use are incomplete, notify the operators and, when necessary, Fimea. For more information about notifying Fimea, see Sections 7.2 (Inform of non-conformities (before distribution of the device)) and 7.4 (Inform of non-conformities (after distribution of a device)) of this document.

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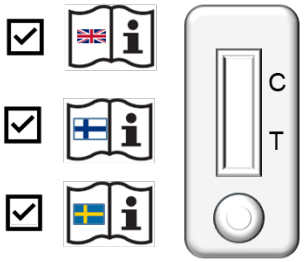
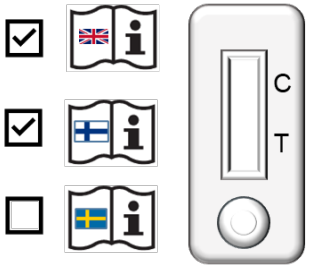
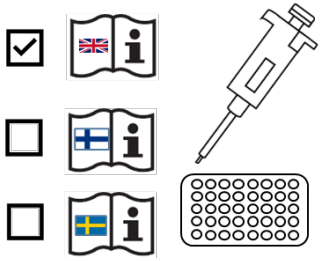
Language requirements for instructions for use

A manufacturer may prepare instructions for use in Finnish, Swedish or English.

NOTE! However, the following information must be provided both in Finnish and in Swedish:

1. Information allowing safe use of the device
2. Instructions for use for devices intended to be used by patients and other consumers

Table 3. Examples of at-home Covid-19 test and laboratory test for Covid-19 and the language versions of the supplied instructions for use

Example 1: At-home Covid-19 test	Example 2: At-home Covid-19 test	Example 3: Laboratory test for Covid-19
		
The at-home test is supplied with instructions for use in English, Finnish and Swedish. In this example, the language requirements are met because the instructions for use for an at-home test can be supplied in other languages besides Finnish and Swedish.	The at-home test is supplied with instructions for use in English and Finnish. In this example, the language requirements are not met because the instructions for use for an at-home test must be supplied at least in Finnish and in Swedish.	A laboratory test for Covid-19 only comes with instructions for use in English. In this example, the language requirements are met provided that information allowing safe use of the device have been supplied both in Finnish and in Swedish.

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7.1.3 EU declaration of conformity

With an EU declaration of conformity, the manufacturer assumes the obligations incumbent on manufacturers under MDR or IVDR as well as the requirements set out in applicable Union legislation.

There is no document template for the declaration, and the declarations of different manufactures look different. The required content is defined in the Regulations, however.

The declaration must include for example the following information

- Name and contact details of the manufacturer;
- A statement that the EU declaration of conformity is issued under the sole responsibility of the manufacturer;
- The UDI-DI;
- Product and trade name, product code, catalogue number or other unambiguous reference allowing traceability of the device;
- Intended purpose of the device;
- Risk class of the device;
- A statement that the device is in conformity with the applied regulation (e.g. MDR or IVDR);
- References to any common specifications (CS) in relation to which conformity is declared;
- Where applicable, information about the notified body (e.g. the route of conformity and the certificate number)
- Place and date of issue of the declaration and signature.

Further information:

- EU declaration of conformity: MDR Annex IV, IVDR Annex IV

7.2 Inform of non-conformities (before distribution of the device)

If the distributor finds or suspects that the device is not compliant, it must always notify the manufacturer and, when necessary, also the authorised representative of the manufacturer and the importer. If the observed non-conformity is related to falsified goods or the distributor suspects that the device may present a serious risk, it must also inform Fimea at: medicaldevice@fimea.fi.

DISTRIBUTION OF THE DEVICE IS NOT ALLOWED BEFORE THE NON-CONFORMITY HAS BEEN REMEDIED!

Terms:

- Authorised representative = an operator who is responsible for certain obligations of a non-EU manufacturer in the EU area
- Importer = an operator established within the Union who imports products from outside the EU on the Union market.
- Falsified device = a falsified device is device whose ID, origin, CE marking or the documents related to CE marking, such as the EU declaration of conformity, are falsified
- Serious risk
  - The term 'serious risk' is not defined in the Regulation. However, the following should be noted:
    - The concept of risk comprises two components: the probability of harm (e.g. recurrent, rare) and its severity (e.g. severe, negligible).
    - Consider the term in relation to "a serious incident". A serious incident can lead to serious harm, such as death or a temporary injury.
    - Next, think about the probability: is it probable that the use of the device will cause serious harm?

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Informing of non-conformity

When should I only inform the manufacturer of a finding?
If the manufacturer of the device is established in a Member State, it does not need an importer or an authorised representative. You only need to notify the manufacturer of a non-conformity.

When should I also inform the authorised representative and the importer?
If the manufacturer of the device is established outside the Union, it must have both an importer and an authorised representative. In that case, you should notify all three of any observed non-conformities.

When should I also inform Fimea?
If you observe or suspect that a device causes a serious risk or that the device is falsified, notify Fimea by sending a free-form email at: medicaldevice@fimea.fi.

Further information:

- Definition of an authorised representative: MDR Article 2(32); IVDR Article 2(25)
- Definition of an importer: MDR Article 2(33); IVDR Article 2(26)
- Definition of a falsified device: MDR Article 2(9); IVDR Article 2(10)
- Definition of risk: MDR Article 2(23); IVDR Article 2(16)

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7.3 Store and transport the device in accordance with the manufacturer's requirements

During the time that a medical device is in the possession of the distributor, the distributor must ensure that the storage and transport conditions required by the manufacturer are met.

Table 4. Examples of symbols related to storage and handling of devices

Symbol (SFS EN ISO 15223-1)	**Meaning**	**Indicated information**
	Do not use if package is damaged	The device should not be distributed if the package has been damaged.
	Store protected from humidity	Protect the device from humidity during storage.
	Fragile, handle with care	The device must be handled with care because otherwise it can be damaged or broken.
	Temperature range	The device must be stored within the allowed temperature range. Temperature can have both an upper and lower limit or only one of these.

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7.4 Inform of non-conformities (after distribution of a device)

If the distributor finds or suspects that the distributed device is not compliant, it must immediately notify the manufacturer and, when necessary, the authorised representative of the manufacturer and the importer.

In such cases, the distributor must cooperate with the manufacturer, authorised representative, importer and authority to implement corrective actions.

Such actions may include

- Bringing the device into conformity;
- Withdrawing the device; or
- Recalling the device.

Terms:

- Recall = any measure aimed at achieving the return of a device that has already been made available to the end user
- Withdrawal = any measure aimed at preventing a device in the supply chain from being further made available on the market

Further information:

- Definition of recall: MDR Article 2(62); IVDR Article 2(65)
- Definition of withdrawal: MDR Article 2(63); IVDR Article 2(66)

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Notifying of a finding

1. When should I only inform the manufacturer of a finding?
If the manufacturer of the device is established in a Member State, it does not need an importer or an authorised representative. You only need to notify the manufacturer of a non-conformity.

2. When should I also inform the authorised representative and the importer?
If the manufacturer of the device is established outside the Union, it must have both an importer and an authorised representative. In that case, you should notify all three of any observed non-conformities.

3. When should I also inform the supervisory authority?
If you find or suspect that a device presents a serious risk, immediately notify the supervisory authorities of the EU countries to which you have distributed the device.

Include at least the following information:

- As detailed description of the non-conformity as possible
- Information about implemented corrective actions

Inform Fimea of your finding at: medicaldevice@fimea.fi

Further information:

- Authorities supervising medical devices in EU Member States: lists of contact details

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7.5 Inform of suspected incidents

A distributor must immediately inform the manufacturer and, where necessary, the manufacturer's authorised representative and importer of suspected incidents concerning the devices supplied by the distributor. A suspicion is enough because the manufacturer is responsible for determining the final root cause.

What is an incident?

An incident is an event where a medical device does not operate as expected. A serious incident is an incident that led or might have led to serious deterioration of the state of health or death of a patient, user or another person.

A distributor must inform of incidents that are caused by or suspected to be caused by the device's

- feature
- undesirable side-effect
- malfunction or a change in performance
- insufficient labelling
- any error or inadequacy in the information supplied by the manufacturer.

Examples of incidents:

- The package of a sterile device has been damaged, and the use of the device could cause an infection for the patient
- Damaged connectors of an electric device cause an electronic shock to the user
- Failure of the device's support structure causes an injury to the user
- The patient is referred to inappropriate treatment due to an incorrect test result

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Why do I have to inform the manufacturer of incidents?

Distributors must inform the manufacturer of suspected incidents to allow the manufacturer to

1. Investigate the root cause of the incident
2. Determine necessary corrective actions (e.g. field safety corrective action, FSCA)
3. Assess who should be informed of the situation (e.g. authorities, importers, etc.)
4. Monitor the number of incidents and possible trends

Terms:

- Field safety corrective action (FSCA) = actions determined by a manufacturer to prevent or reduce the risk of a serious incident in relation to a device made available on the market. The manufacturer communicates of a FSCA with a field safety notification (FSN).

Table 5. Examples of FSCAs determined by a manufacturer and their possible impacts on distributors.

Manufacturer's FSCA	Impacts on distributor's actions
Recall of devices	Participate in the recall
Modification of the device, instructions for use or labels	Check the labels to make sure that the changes have been taken into consideration
Disposal of devices	Dispose of the devices in accordance with the manufacturer's instructions

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Reporting of adverse incidents

If the manufacturer of the device is established in a Member State, it does not need an importer or an authorised representative. You only need to notify the manufacturer of the incident. If the manufacturer of the device is established outside the Union, it must have both an importer and an authorised representative. In that case, you should notify all three operators of the incident.

Provide the manufacturer with as detailed description of the device and the observed incident as possible. Below is a list of examples of information to include:

- ☑ Information necessary for the identification of the device (e.g. a batch or serial number)
- ☑ A description of the incident (e.g. what, where, when and to whom)
- ☑ Actions taken by the distributor (e.g. device taken to storage, a replacement device supplied)

Always remember to follow the manufacturer's instructions.

Further information:

- Definition of an incident: MDR Article 2(64); IVDR Article 2(67)
- Definition of a serious incident: MDR Article 2(65); IVDR Article 2(68)

7.6 Keep a register of complaints, non-conforming devices and of recalls and withdrawals

Distributors must keep a register of complaints, non-conforming devices and of recalls and withdrawals. They also must keep the manufacturer and, where applicable, the authorised representative and the importer up to date of this monitoring. This information is entered in the post-market surveillance system of the manufacturer.

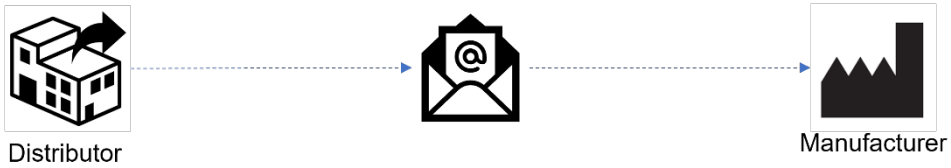
A post-market surveillance system means a system which the manufacturer has set up in cooperation with other economic operators (e.g. importers, distributors) to proactively collect and review information about devices they manufacture for the purpose of identifying any need to apply any corrective or preventive actions.

A manufacturer uses this information to, for example

- Update instructions for use and labels
- Improve the usability, performance and safety of devices
- Detect trends
- Determine any preventive and corrective actions and field safety corrective actions.

Further information:

- Post-market surveillance system of the manufacturer: MDR Article 83, IVDR Article 78



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7.7 Co-operate with authorities

A supervisory authority, such as Fimea, may make the following requests to distributors:

1. **Demonstrating conformity of the device:**
   An authority may request a distributor to submit information and documents necessary to demonstrate the conformity of the device. Such documents may include: EU declaration of conformity, instructions for use, information about the device labels, information about the clinical investigation of the device or a risk analysis. The distributor is considered to have met this obligation when the manufacturer or authorised representative has submitted the requested information.

2. **Elimination of risks presented by the device**
   An authority may request the distributor to cooperate to eliminate risks presented by distributed devices. This may include, for example, informing of customers/users, cessation of the sale, marketing and distribution of the device and recall.

3. **Granting access to the device to assess conformity:**
   An authority may require the distributor to provide a sample of the device or otherwise grant access to the device.

8 Marketing

A distributor must ensure that the marketing of medical devices meets the following requirements:

1. Correct terms are used in marketing;
2. Information about the manufacturer and device have been provided;
3. The device is marketed in accordance with its intended purpose;
4. Marketing does not convey a false impression of the device features;

These requirements must be met regardless of the format of the promotional material.

8.1 When can I use the term ‘medical device’?

Promotional material for a medical device must always indicate that it is a CE marked medical device.

NOTE! Only medical devices can be marketed using the term ‘medical devices’.

Table 6. Examples of the use of the term ‘medical device’ in marketing.

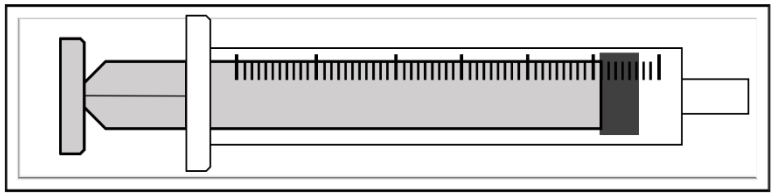
Examples	Example 1	Example 2	Example 3
An example device			
Name of the device	surgical face mask	surgical face mask	Protective personal equipment
Has it been indicated that the product is a medical device?	Yes	No	Yes
Does marketing conform to the requirements?	Yes	No	No

8.2 What information should I provide about the device and the manufacturer?

Provide the manufacturer and the product or trade name given by the manufacturer in the promotional material.

Where a certificate from a notified body is required for the device, the number of the notified body that issued the certificate must also be given in connection with the marketing.

Front



Back

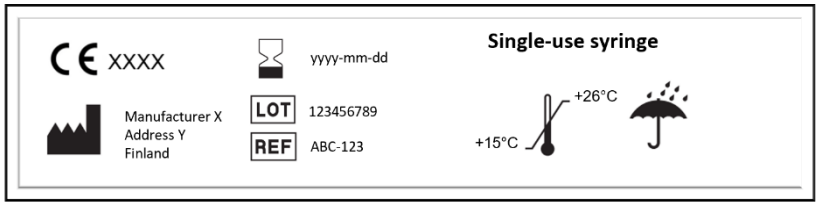


Figure 10 An example of a single-packaged syringe. Promotional material for the type of device depicted in the figure must state the manufacturer (Manufacturer X) and the trade name of the device (Single-use syringe). As you can see, the CE marking on the label is followed by the number of notified body (XXXX). This number must be stated in the promotional material for the device.

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8.3 What does the intended purpose of the device mean?

The manufacturer of the device must define the use for which a device is intended.

The intended purpose may convey for example the following information:

- User group (children vs. adults, laypersons vs. professional users)
- Function of the device (e.g. treatment, alleviation, diagnosing, monitoring, etc.)
- Type of sample (e.g. saliva, urine, blood, etc.)

IT IS NOT ALLOWED TO MARKET THE DEVICE FOR ANY OTHER PURPOSE THAN THE INTENDED PURPOSE DEFINED BY THE MANUFACTURER

Example (see figure 7):

- Intended purpose determined by the manufacturer: At-home test for adults to detect antigen ABC to facilitate diagnosis of disease D.
- That means the device cannot be marketed:
  - To children
  - For detecting antigens other than antigen ABC
  - To any other purpose than facilitating the diagnosis of disease D

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8.4 What kind of marketing may convey a false impression?

Marketing of medical devices must not mislead consumers about the intended purpose, safety or performance of the device.

The following are not allowed in marketing:

1. Attributing to the device functions and features that it does not have;
2. Creating the wrong impression regarding treatment or diagnosis, functions or properties that the device does not have;
3. Failing to inform of the potential risk associated with the use of the device in accordance with its intended use;
4. Leading people to assume that the device can be used for any purpose other than its intended purpose.

8.5 What is considered promotional material?

Promotional material can come in many formats. It can be, for example, printed material, a voice, a video commercial, an email or other visual or verbal presentation.

Examples of promotional material:

- Press release
- Websites
- Brochures
- Abstracts
- Scientific posters
- Posters, publications
- Video presentations

9 Questions presented to Fimea (Q&A)

This section includes questions presented to Fimea. The questions have been grouped by topic.

A. Roles
   a. Am I a distributor or importer when the manufacturer operates both in and outside the EU?
   b. On the use of the term ‘marketer’

B. Checking labels, instructions for use and the EU declaration of conformity
   a. Applying a sampling method
   b. Can an authorised representative or manufacturer carry out checks on behalf of distributors?
   c. Is the device regulated by a directive or a regulation?

C. Questions about transferring the obligations of the manufacturer to the distributor
   a. Cases that are not considered modification of a device
   b. Selling a device under your own trademark

D. Measures that require the permission of the manufacturer

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Am I a distributor or importer when the manufacturer operates both in and outside the EU?

The manufacturer of a device is marked on the EU declaration of conformity and the device/package/ instructions for use. Assess your role in the supply chain based on this information about the manufacturer and not the physical site of manufacture, for example.

The use of the term ‘marketer’

Regulations on medical devices (both MDR and IVDR) identify the following roles and obligations in the supply chain:

- Manufacturer, see general obligations MDR/IVDR Article 10
- Importer, see general obligations MDR/IVDR Article 13
- Distributor, see general obligations MDR/IVDR Article 14

The Regulations do not recognise a role called ‘Marketer’. However, the term can be used on the device packages and/or instructions for use, provided that the information about the manufacturer (and the authorised representative and importer, where applicable) has been marked unambiguously and in accordance with the requirements.

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Applying a sampling method

To meet certain requirements, distributors may apply a sampling method that is representative of the devices supplied by that distributor for the purpose of conformity assessment. To ensure that the sample is representative, the distributor must make sure that no group is systematically favoured or excluded from the sample.

You can apply a sampling method for checking the conformity of:

- CE marking
- EU declaration of conformity
- Labelling and instructions for use
- UDI

You cannot apply a sampling method for checking information provided about the importer. Check the following for supplied devices:

- The importer is indicated on the device, package or the documentation accompanying the device
- Importer's additional label does not obscure any information provided by the manufacturer

Can an authorised representative or manufacturer carry out checks on behalf of distributors?

All operators in the supply chain must perform their obligations in accordance with the Regulations. In other words, a distributor cannot transfer its obligations or its responsibility to check the conformity of devices to upstream operators.

Further information:

- MDCG guidance on the implementation of Articles 13 and 14: MDCG 2021-27 Rev.1

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Is the device regulated by a directive or a regulation?

The applicable legislation, i.e. is the device a MD or an IVD and is it regulated by a directive or a regulation is given in the EU declaration of conformity. This information is also recorded in the EUDAMED database.

In Finland, MDs and IVDs are regulated by a national law on medical devices (719/2021): link

Table 7. Regulations and directives on MDs and IVDs and the dates of application.

Device	Applicable legislation	Abbreviation	Date of application
Medical device (MD)	Medical Device Directive 93/42/EEC (Directive concerning medical devices)	MDD or MD Directive	Ceased to apply on 25 May 2021
Medical device (MD)	Medical Device Regulation: EU/2017/745 (Regulation on medical devices)	MDR or MD Regulation	Starting from 26 May 2021
In vitro diagnostic medical device (IVD)	Directive on in vitro diagnostic medical devices 98/79/EC (IVD Directive)	IVDD or IVD Directive	Ceased to apply on 25 May 2022
In vitro diagnostic medical device (IVD)	Regulation on in vitro diagnostic medical devices 2017/746 (IVD Regulation)	IVDR (*IVD Regulation)*	Starting from 26 May 2022

Further information:

- Fimea website: Frequently asked questions about the Regulations (in Finnish)

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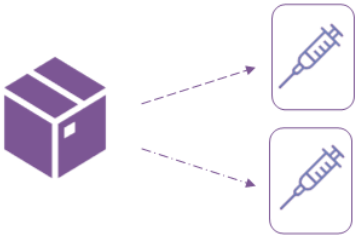
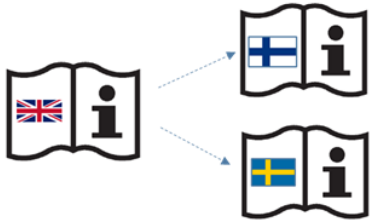
Cases that are not considered modification of a device

In the following cases, a distributor does not assume responsibility for the manufacturer's obligations:

1) **Changing the package size:** A distributor can make changes to the outer package or package size of a medical device. Repackaging cannot affect the original condition of the device.

2) **Translating of information:** A distributor can translate, for example, the instructions for use drawn up by the manufacturer to comply with national language requirements.





HOWEVER, DISTRIBUTORS MUST HAVE A QUALITY MANAGEMENT SYSTEM TO ENSURE THAT THE MEASURES DO NOT AFFECT THE ORIGINAL QUALITY OF THE DEVICE (see next page).

However, distributors must have a quality management system to ensure that the measures do not affect the original quality of the device. Do this before you distribute devices in Finland:

1. Indicate on the device, package or instructions for use that you have made changes to the device (translated information or changed the package size). Add your name and contact details.

2. Check that a quality management system and necessary methods are available to ensure that
    a. Changing the package size does not affect the device's original condition/the translated information is correct and up to date;
    b. You will receive information about corrective actions implemented by the manufacturer.

3. Inform the manufacturer and Fimea (medicaldevice@fimea.fi) of changing the package size or translating information at least 28 days before distribution. Submit a certificate on the quality management system issued by a notified body to Fimea.

Further information:

- Cases in which obligations of manufacturers apply to distributors: MDR Article 16, IVDR Article 16
- MDCG guidance on repackaging and relabelling: MDCG 2021-26

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Selling a device under your own trademark

A distributor/importer must assume the obligations incumbent on manufacturers if it distributes/sells the device under its name, registered trade name or registered trademark.

NOTE! Does not apply to situations where a distributor/importer enters into an agreement with a manufacturer whereby the manufacturer is identified as such on the label and is responsible for meeting the requirements placed on manufacturers in the Regulation.

Further information:

- Cases in which obligations of manufacturers apply to distributors: MDR Article 16, IVDR Article 16
- MDCG guidance on repackaging and relabelling: MDCG 2021-26

When does a distributor require permission from the manufacturer?

A distributor must always obtain permission from the manufacturer for the following measures:

1. Preparing your own instructions for use
2. Translating instructions for use prepared by the manufacturer
3. Changing the package, e.g adding labels/stickers
4. Changing the package size
5. Using your own brand for the device

A distributor cannot independently change the intended purpose of the device