NEW MEDICAL DEVICE REGULATION:
DEFINITIONS, ROLE AND RESPONSIBILITIES FOR IMPORTERS AND DISTRIBUTORS IN PORTUGAL

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REPÚBLICA PORTUGUESA
SAÚDE

SNS SERVIÇO NACIONAL DE SAÚDE

Infarmed
Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.

AGENDA

MEDICAL DEVICES LEGAL FRAMEWORK

NEW

Medical Devices Regulation - (UE) 2017/745 (MDR)

May 2021

- **Dir 90/385/CEE – Active Implantable MD**
- **Dir 93/42/CEE - MD**
- **Dir 2007/47/CE**

DL nº145/2009

***In vitro Diagnostic Medical Device* – (UE) 2017/746 (IVDR)**

May 2022

Dir 98/79/CE - In-vitro Diagnostic MD

DL nº189/2000

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NEW EU MD REGULATIONS

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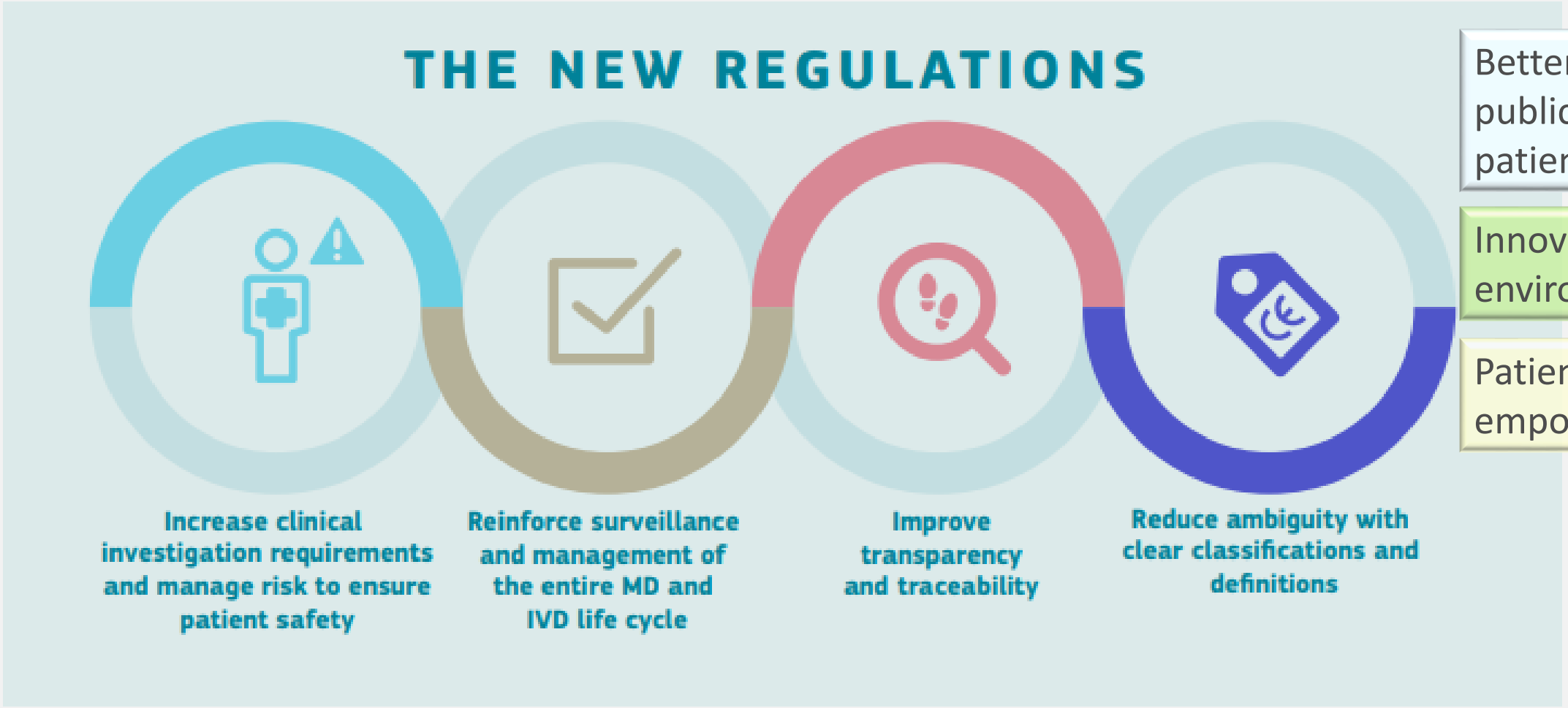
MEDICAL DEVICES REGULATIONS (MDR & IVDR)



Better protection of public health and patient safety

Innovation-friendly environment

Patient empowerment

https://ec.europa.eu/docsroom/documents/34908

MEDICAL DEVICES REGULATION (MDR)

The scope of the MDR has broadened

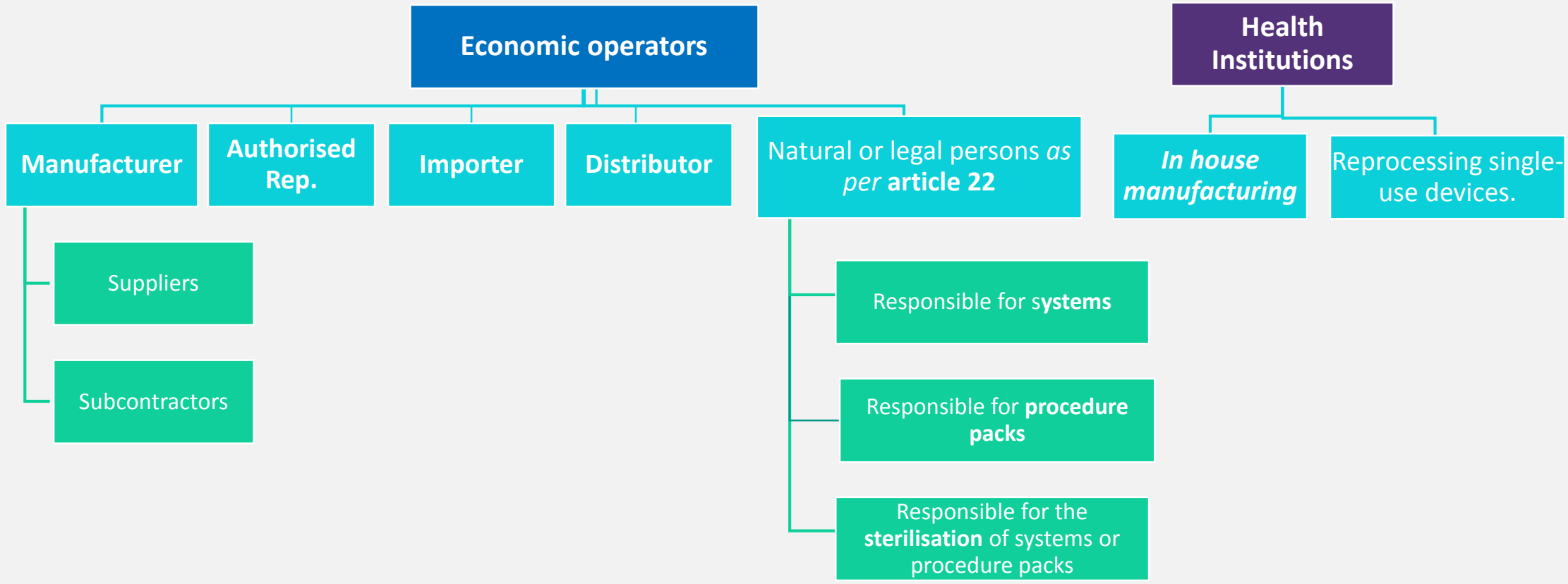
+ More products can fall within the definition of MD;
+ Devices for the control or support of conception;
+ Products specifically intended for the cleaning, disinfection or sterilisation of devices;
+ Devices with non-medical intended purpose listed in Annex XVI.

- Contact lenses or other items intended to be introduced into or onto the eye.
- Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty.
- lasers and intense pulsed light equipment, for skin resurfacing, for tattoo or hair removal or other skin treatment.
- Equipment intended for brain stimulation (…

It is now explicit that devices and services sold online fall under the MDR scope

MEDICAL DEVICES REGULATION (MDR)

More entities are covered



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ECONOMIC OPERATORS

ECONOMIC OPERATORS

New EU Regulations

- Present new definitions: *economic operators*, *manufacturers*, *authorised representatives*, *importers* and *distributors*;
- Establish in detail the general obligations of economic operators in the context of regulatory compliance, taking into account their activities;
- Adapt the obligations of the new "New Legislative Framework for the Marketing of Products"*

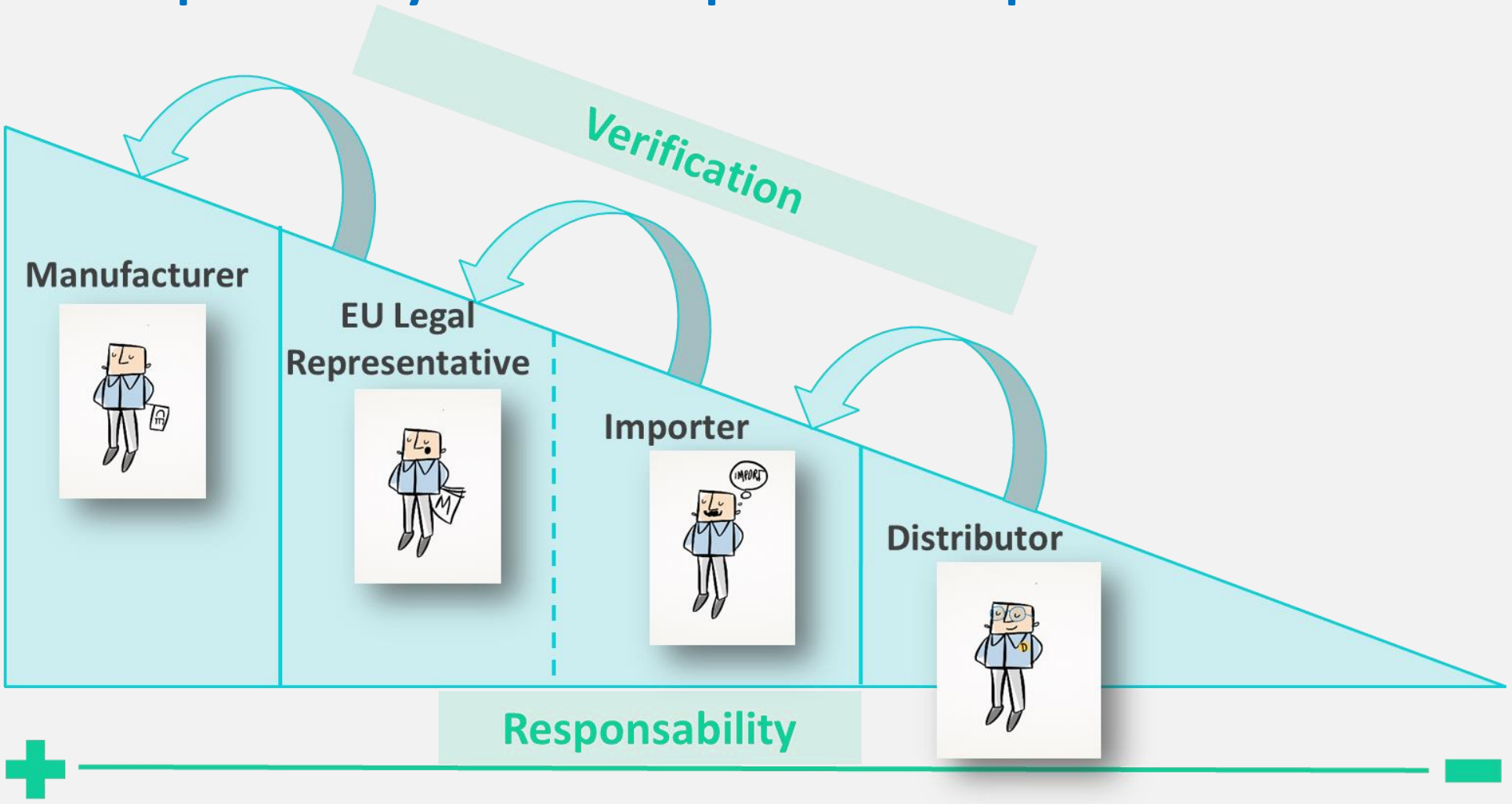
*

Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82).

ECONOMIC OPERATORS

Cascade of Responsibility and Retrospective Compliance Verification



ECONOMIC OPERATORS

Definitions	MDR and IVDR *Article 2.* **Definitions**	Current national legislation
Economic Operator	'**economic operator**' means a manufacturer, an authorised representative, an importer, a distributor or the person referred to in Article 22(1) and 22(3);	—
Manufacturer	'**manufacturer**' means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark;	✓
Authorised Representative	'**authorised representative**' means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation;	✓
Importer	'**importer**' means any natural or legal person established within the Union that places a device from a third country on the Union market;	—
Distributor	'**distributor**' means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service;	✓ *Wholesale distributor

ECONOMIC OPERATORS

Definitions

"Economic operator" means a manufacturer, an authorised representative, an importer, a distributor or the person referred to in Article 22(1) and 22(3);

Article 22(1) and 22(3):

- Any Natural or legal persons that combine devices bearing a CE marking with other devices or products, in compliance with their applicable legislation in order to place them on the market as a system or procedure pack;

- Any natural or legal person who sterilises systems or procedure packs

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EO ROLES AND RESPONSABILITIES - MANUFACTURER

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ECONOMIC OPERATORS - MANUFACTURER

“manufacturer” means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark;

However, the Regulation foresees (article 16) the possibility of making available on the market a device under a distributor or importer name, trade name or trademark if:

- an agreement was established with the manufacturer and
- the manufacturer is identified as such on the label, IFU and promotional material and
- the manufacturer is still responsible for meeting the requirements and for the conformity of the MD (EU declaration of conformity and certificate of conformity under his name);

ECONOMIC OPERATORS - MANUFACTURER

The manufacturer must comply with the MDR.

The manufacturer should assess the conformity of his device – a process that may require the involvement of a Notified Body. Other important points to include:

- ❑ Clinical evaluation
- ❑ Risk management
- ❑ Quality Management System (QMS)
- ❑ UDI system
- ❑ Post-market surveillance/Vigilance
- ❑ Technical documentation and other reports
- ❑ Liability for defective devices.
- ❑ Registration at EUDAMED (devices and actors/economic operators).
- ❑ A person responsible for regulatory compliance

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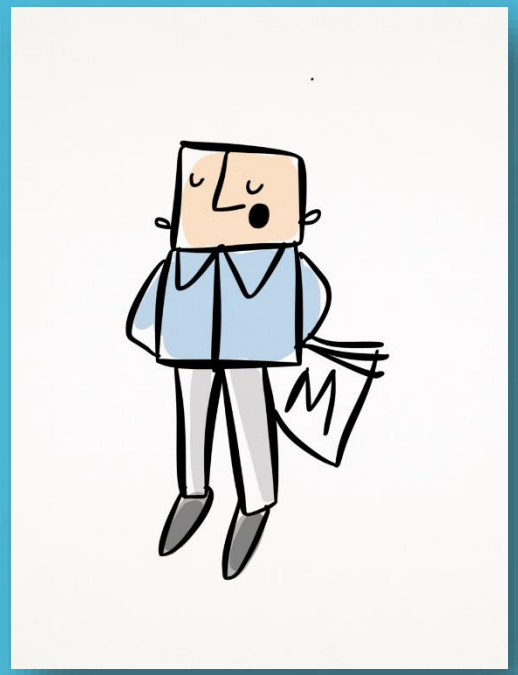
EO ROLES AND RESPONSABILITIES
- AUTHORISED REP. -



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ECONOMIC OPERATORS - AUTHORISED REPRESENTATIVE

‘authorised representative’ means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation;

Written mandate - The Regulations also describe:

- the tasks that can be delegated to the authorised representative, and the conditions under which this can take place. This relationship should be covered by a precise mandate.
- activities that cannot be delegated to an authorised representative.
- detailed rules for specific situations. (…)

ECONOMIC OPERATORS - AUTHORISED REPRESENTATIVE

At a minimum, authorised representatives' obligations include:

- verifying that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer
- To keep copies available of all documents and make them accessible to authorities on request. This includes technical documentation, declarations of conformity, and certificates, including their amendments and supplements
- To verify that the manufacturer has registered the requested information in EUDAMED;
- Cooperate with Competent Authorities (…)

Active role - Post-market surveillance/Vigilance

Should have permanent and continuous access to a person responsible for regulatory compliance

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EO ROLES AND RESPONSABILITIES
- IMPORTERS-

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ECONOMIC OPERATORS - IMPORTER

'**importer**' means any natural or legal person established within the Union that places a device from a third country on the Union market;

General obligations*:

- Importers shall place on the market only devices that are in conformity;
- The importer should verify the following:
  - To make sure that the devices they place on the market bear the CE marking and if a EU declaration of conformity was draw up;
  - If an Authorised Rep was designated;
  - That MDs are accompanied by the required information and labelled in accordance with the Regulation,

* MDR/IVDR Article 13

ECONOMIC OPERATORS - IMPORTER

NEW

General obligations*:

- The importer should verify the following (cont.):
  - That a UDI have been assigned (where applicable). In addition, the importer should verify that devices are registered in EUDAMED and if any information related to authorised rep is missing.
  - Liaise with authorised rep or manufacturer for issues related to EUDAMED data.
- have the responsibility to inform manufacturers and their authorised representatives in the event of complaints and if he considers that a device is not compliant with the Regulations.
- make sure that storage and transport conditions, when under their responsibility, do not jeopardise compliance.

* MDR/IVDR Article 13

ECONOMIC OPERATORS - IMPORTER

General obligations*:

- indicate on the device or its packaging, or in a document accompanying the device, their name, registered trade name or registered trade mark, their registered place of business and the address at which they can be contacted.
- Active role on Post-market surveillance/Vigilance – by keeping a register of complaints, non-conforming devices, recalls and withdrawals, and escalate non-compliance to authorities if they suspect that a device has been falsified or that there is a serious risk to health.
- Are required to cooperate with authorities and provide samples or grant access to the devices

(…)

* MDR/IVDR Article 13

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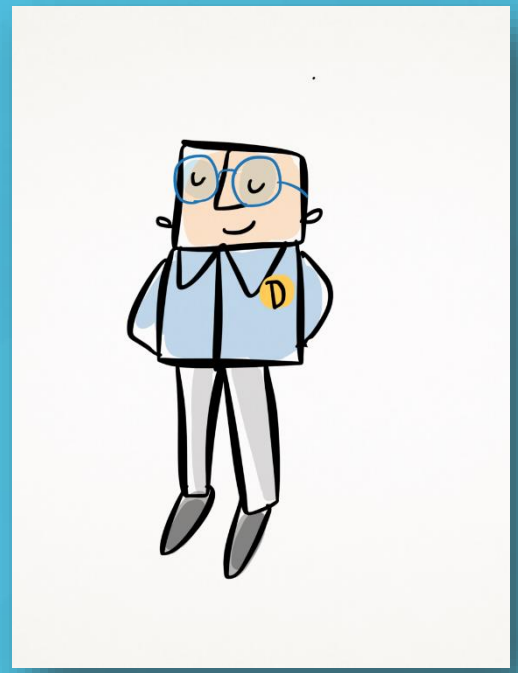
EO ROLES AND RESPONSABILITIES
- DISTRIBUTOR-



ECONOMIC OPERATORS - DISTRIBUTOR

'**distributor**' means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service;

MDR

wholesale and retail distributors

National legislation

wholesale distributors (including importers)

ECONOMIC OPERATORS - DISTRIBUTOR

General obligations*:

- should make sure that the devices they distribute are compliant with the obligations described in MDR/IVDR Article 14. Distributors should verify the following:
  - that the devices have been CE marked,
  - that an EU Declaration of Conformity has been drawn up, and
  - that labels and instructions for use (MDR/IVDR Annex 1 section 23) are provided in the official languages of the Member States in which the device is made available (or in languages accepted by those Member States).
  - Distributors should also verify that the importer's name is indicated on each device or in the accompanying documentation, and that the device bears a UDI.

the distributor may apply a sampling method that is representative of the devices supplied

* MDR/IVDR Article 14

ECONOMIC OPERATORS - DISTRIBUTOR

General obligations*:

- shall ensure that storage and transport conditions, when under their responsibility, are appropriate and in line with the recommendations of the manufacturer.
- If a distributor considers a device to be non-compliant with the Regulations, the device shall not be made available on the market. In this case, the distributor should inform the other economic operators.

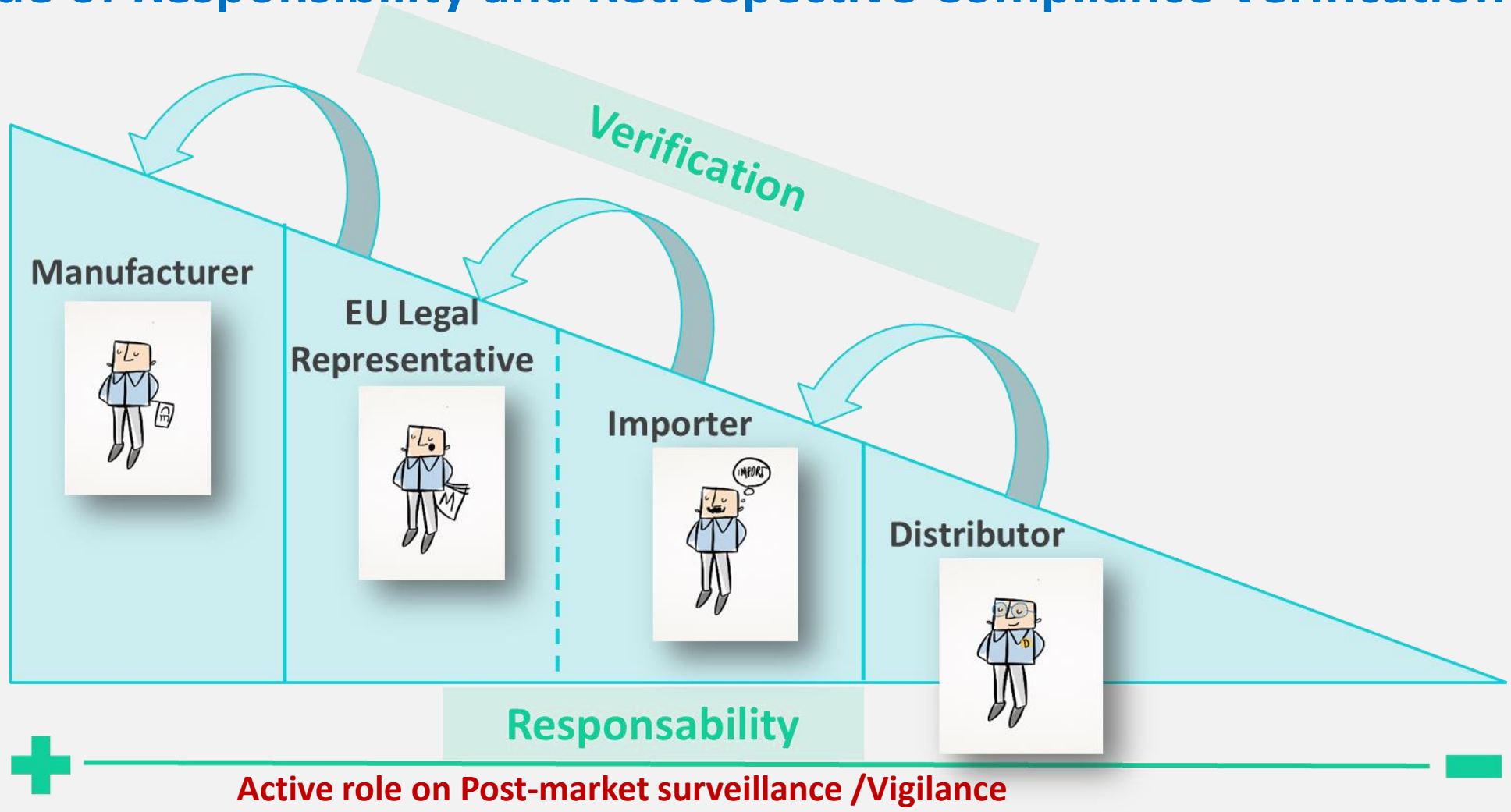
Active role on Post-market surveillance/Vigilance

- should inform the authorities if they suspect that a device has been falsified or that there is a serious risk to health.
- They should also keep a register of complaints, non-conforming devices, recalls and withdrawals. Distributors shall cooperate with authorities and make available all the documentation and information they have at their disposal.

* MDR/IVDR Article 14

ECONOMIC OPERATORS

Cascade of Responsibility and Retrospective Compliance Verification



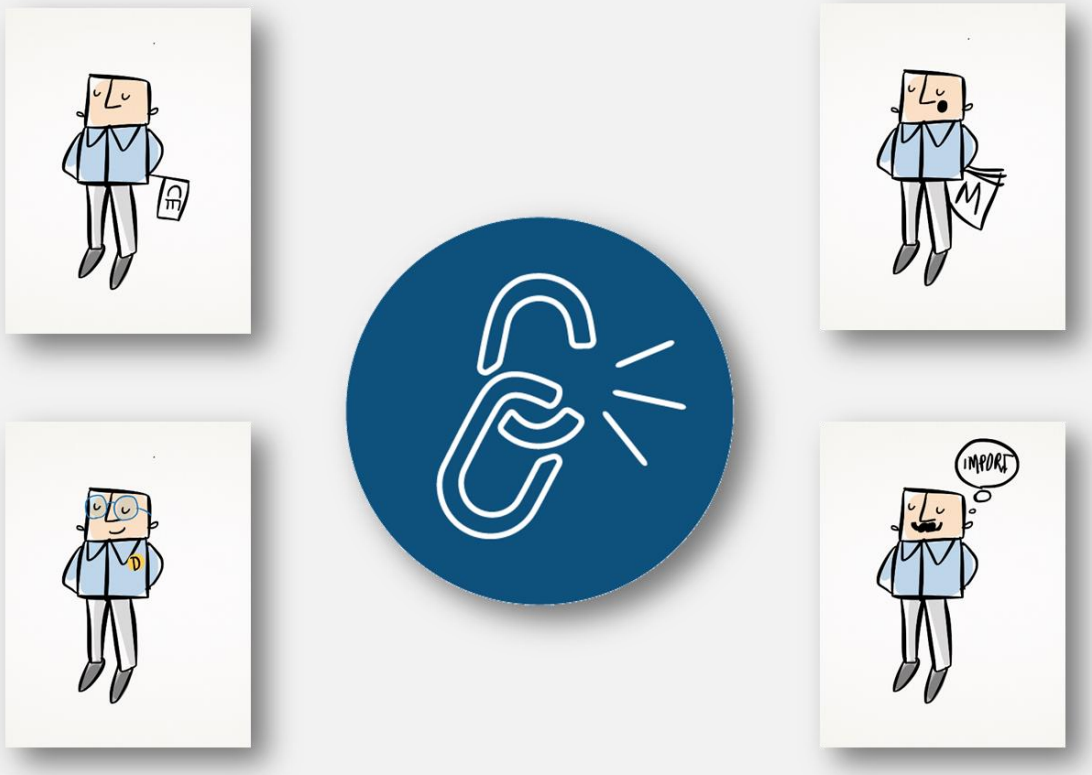
ECONOMIC OPERATORS

Cases in which obligations of manufacturers apply to importers or distributors:

MDR/IVDR **Article 16**

- makes available on the market a device under its name, registered trade name or registered trade mark
- changes the intended purpose of a device already placed on the market or put into service;
- modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected.

The roles and responsabilities of EO have been clarified and reinforced to ensure the legal compliance of devices on the market



For a successful implementation:

- Knowledge of the new regulation and alignment with the common understanding of the new definitions and requirements
- Optimization of resources and processes.
- Communication and staff training.
- Cooperation and collaboration - Involvement in European and national discussion.

OBRIGADA
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