

The logo for MedEnvoy, featuring the word "medenvoy" in a lowercase, sans-serif font. The "med" is in blue, "envoy" is in gold, and the "o" is a stylized globe icon with blue and gold segments.

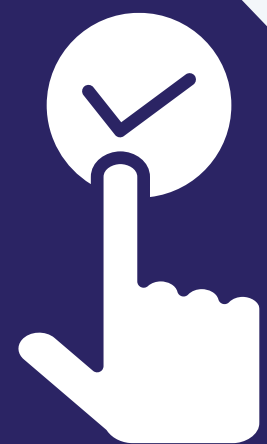
medenvoy

The Role of the Regulatory Importer: Compliance, Responsibilities, and Best Practices

www.MedEnvoyGlobal.com

About Us

Established and led by experienced and reputable regulatory affairs executives, MedEnvoy is dedicated to supporting medical device companies with compliance in their international expansion.

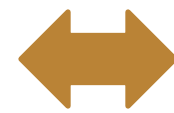


**MedEnvoy is EN ISO 13485
certified!**



Key Services

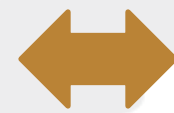
In Country Representation



Regulatory Importer



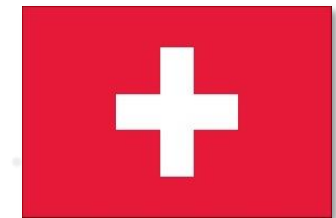
Post Market Surveillance



Consulting services

Regulatory & Quality Management

Markets in Scope



Importer as an Economic Operator

EU MDR/IVDR ARTICLE 2

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

MDR/IVDR ARTICLE 13

General obligations of importer.

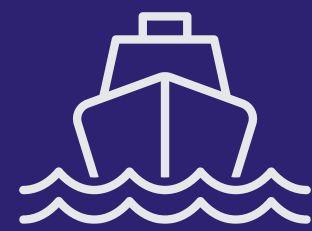
Authorized Representative

Manufacturers

Distributors

Importer

Importation Process



Physical

Shipments via air/sea to Union



Fiscal

Customs & VAT handling in Union



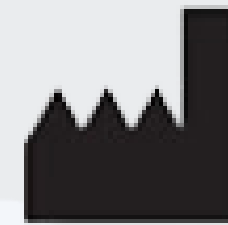
MDR/IVDR

Legal access to Union market

Strategies for meeting importer obligations effectively

Who can be importer?

- ✓ EU-based legal entity of Legal Manufacturer
- ✓ European Authorized Representative - EAR
- ✓ Distributor(s)
- ✓ 3rd Party Logistics Services Provider(s)
- ✓ (Independent) Importer(s)



EC REP



Warehouse

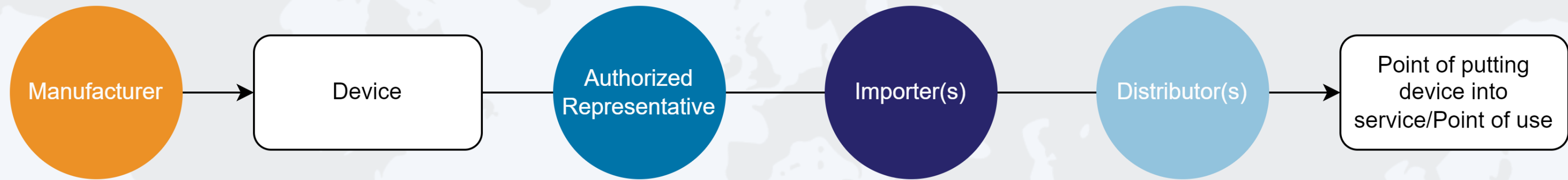


Pick, Pack
& Ship



Delivery

Importer as an Economic Operator



Importer
Any natural or legal person established within the Union that places a device from a third country on the Union market.
(MDR Article 2(33))

Placing on the Market
The first making available of a device, other than an investigational device, on the Union market.
(MDR Article 2(28))

Distributor
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 Article 2(34))

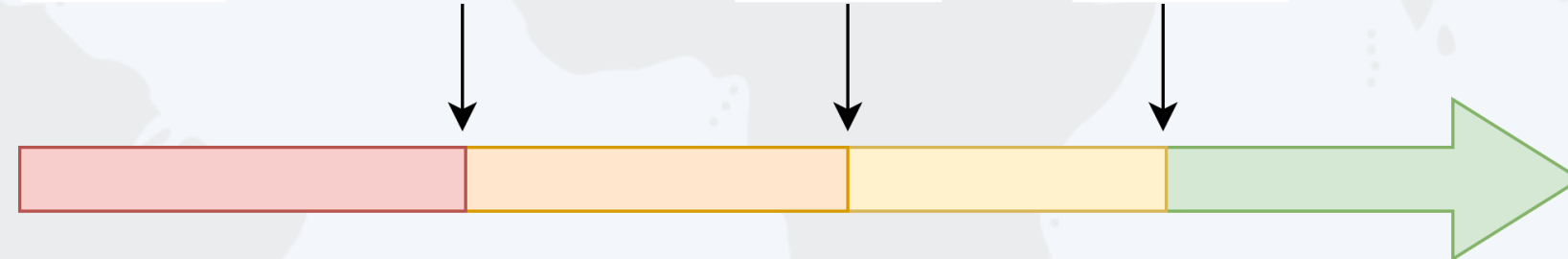
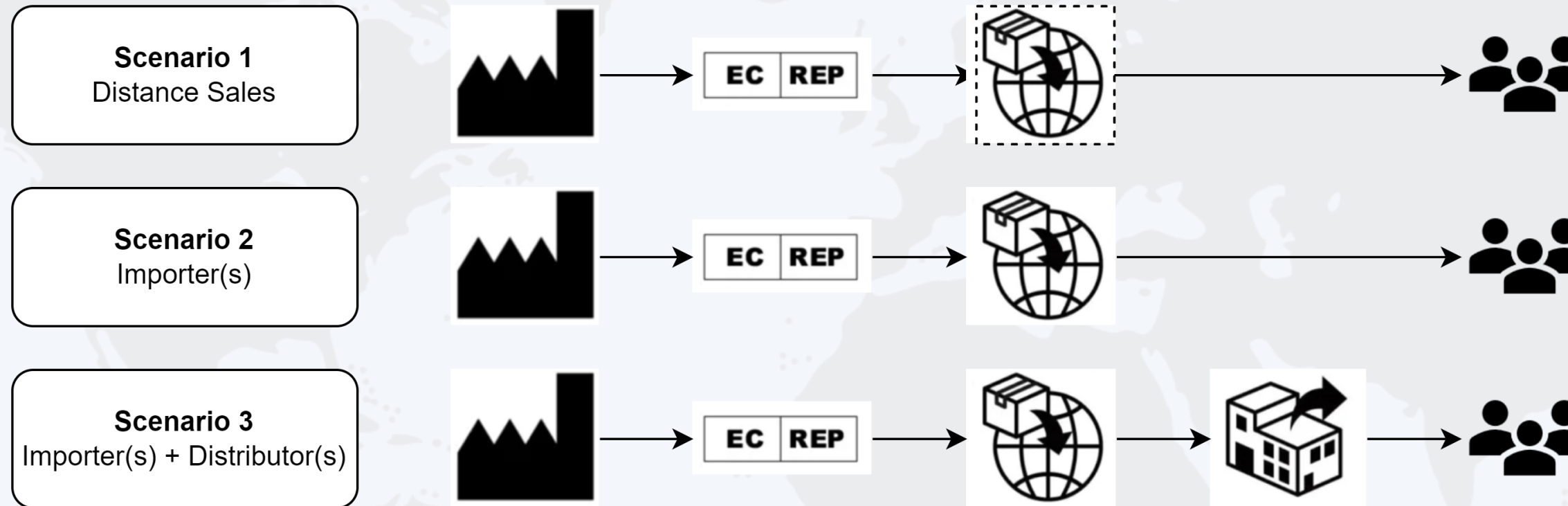
Making available on the Market
Any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge.
(MDR Article 2(27))

Point of Use

Health institution
Organisation the primary purpose of which is the care or treatment of patients or the promotion of public health.
(MDR Article 36)

User
Any healthcare professional or lay person who uses a device.
(MDR Article 37)

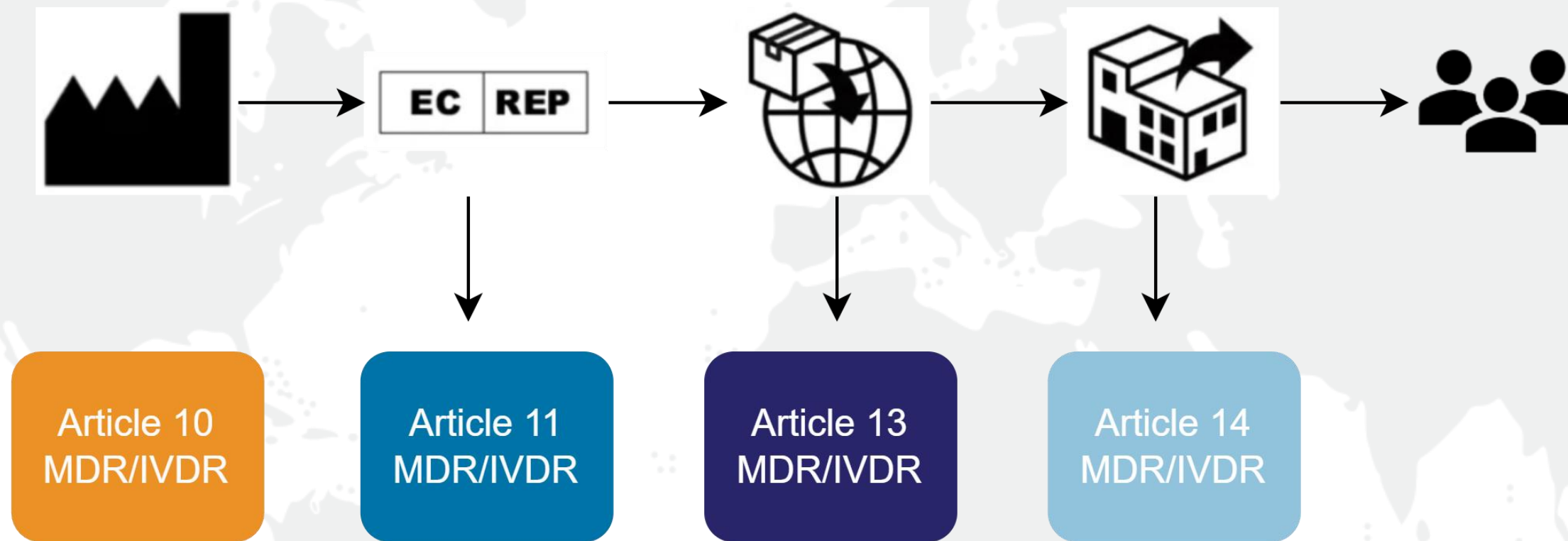
Importer as an Economic Operator



Change due to implementation of the MDR/IVDR
 Clear obligations of the different economic operators including importer and distributor
 Provisions ensuring transparency and traceability of medical devices

EUDAMED
 Data on devices on the market, relevant economic operators, conformity assessment, Notified Bodies, Certificates, etc.

Importer as an Economic Operator



Verification:

- Declaration of Conformity (and CE certificate)
- Technical Documentation
- Appropriate conformity assessment procedure
- Compliance with registration obligations as per Article 27 and 29

Identification:
AR identified on the label and in EUDAMED.

Verification:

- Device CE marked
- Declaration of Conformity
- Manufacturer identified and AR designated.
- Devices labelled as per MDR and accompanied by required IFU
- UDI assigned by manufacturer as per Article 27 and registered in EUDAMED

Identification:
Importer identified on device, packaging or document accompanying the device and in EUDAMED.

Verification:

- Device CE marked
- Declaration of Conformity
- Importer identified.
- IFU in correct language
- UDI assigned

Identification:
No labeling requirement. Distributor no actor registration in EUDAMED.

Obligations Regulatory Importer

Each importation into Union:

✓ Verify:

- CE marking
- EU Declaration of Conformity
- Identification of EAR, Importer and Manufacturer
- Labeling per Regulation incl. IFU
- UDI assignment by manufacturer
- Device registration in EUDAMED*

✓ Check Transport & Storage conditions

✓ Track Shipments within EU

When applicable:

✓ Maintain records of complaints, recalls and withdrawals

✓ Forward any complaints from healthcare professionals, patients or users about suspected incidents to the manufacturer and the authorized representative

✓ Cooperate with NCAs on FSCAs and provide samples/grant access to the device



Obligations Regulatory Importer

Only place a device on the Union market that complies with the MDR/IVDR.

Register in EUDAMED as economic operator (MDR Art 31, IVDR Art 32) and keep information up to date.

Keep copy of EU DoC, copy of CE certificate including any amendments and supplements for at least 10 years*.

* 15 years for implantable devices.

Communicate in case of non-compliance

- If the device is considered not in conformity with Regulation inform the manufacturer and the EAR.
- If the device is considered not in conformity with Regulation and presenting a serious risk or is a falsified device inform the manufacturer, EAR and Competent Authority of the Member State of the Importer.
- If non-conforming device is placed on the market and is considered to present a serious risk inform the manufacturer, EAR, NCAs and NB, if applicable.

References: [MDCG 2021-25](#) and [MDCG 2021-27 \(Rev.1\)](#)

Labeling requirements



MDR/IVDR

- Identification of the importer on the device or on its packaging or in a document accompanying the device*.
- Responsibility of the importer but can be sub-contracted.
- Labeling shall be in place before placing a device on the market.

Legacy devices

- At the discretion of the manufacturer (based on Section 2 of MDCG 2021-27)
- Advised to include identification of the importer to ensure that their location can be established in case of complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device.



MedDO/IvDO

- Identification of the importer on the device or on its packaging or in a document accompanying the device.



UK MDR

- At the discretion of the manufacturer (no MHRA requirement to include the UK importer for both CE marked devices as well as UKCA marked devices).

* Accompanying device must reach the end user (MDCG 2021-27)

Common Deficiencies

Based on inspections of 30 importers by Swissmedic in 2023

- **Product Verification:** 18 out of 30 importers performed incomplete product checks (60%).
- **Contact Details:** 8 out of 30 importers had incomplete importer information (27%).
- **Storage and Transport:** 8 out of 30 importers had inadequate storage and transport conditions (27%).
- **Complaint Handling:** 3 out of 30 importers had deficiencies in recording and forwarding complaints (10%).

Common Deficiencies (2)

Based on information from Notified Body audits / Issues raised by Competent Authorities

- **Declarations of Conformity:** Signed after the DoA of the MDR.
- **Shipment data collection incomplete:** Mandatory data elements missing (e.g. UDI information).

Q&A





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Thank you

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