Economic Operators

Authorised Representatives
Distributors
Importers

Peter Löwendahl
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We are Authorised representative SNR - SE-AR-000001888

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The Authorised Representative

Consider the following before taking on the responsibility

- Insurance coverage
- Ensure access to required documentation
- Need for audits?

- Monitor the company you represent,
  - Things can change quick!!

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Importer or Distributor consequences for you?

- Regulations do not specific request a quality system, but:
  - Indirect needed to meet requirements
  - You need to ensure your processes take care of this

- How to handle MDD vs MDR products since transition timelines will differ between products
- How do you control items that are direct shipped to customer

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Importer requirements

Responsibility includes:

- Devices are CE marked
- Declaration of Conformity exist
- Labels and IFU exist
- Importer name exist on device or IFU
- The product is registered in EUDAMED database
- Storage and transportation meets manufacturers requirements
- Products marked with UDI (if applicable)

Rerouted shipments can make you the importer

- Keep register of recall, complaints, non conforming products
- Traceability of to whom you have provided devices

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Importer must verify that….. (Article 13)

- Prepare yourself on what will be needed
  - Create a procedure/checklist on what to do
  - Who shall do it, where/when
  - Where to place your name/address etc and in what way
- If you don't know what to do talk with someone that knows

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Distributor requirements

- This is regardless if the product is imported or not
- Applies to all parts of the distributor chain

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Distributor must verify that…. (Article 14)

- Device is CE marked
- DoC exist for the products you distribute
- The labels and IFU have right language(s)
- Importers name exist on device or IFU
- Secure storage and transportation meets manufacturers requirements
- Keep register of recall, complaints, non-conforming products
- Traceability of to whom you have provided devices

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Labeling and promotion

- Must promote devices in line with manufacturers CE marking
- Translation must be done in the manufacturers process otherwise you need a Notified Body
- You cannot create your own short version of IFU!

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Guidance and resources

CAMD Overall responsible for implementation lead by Helena Dosiz Swedish MPA

https://www.camd-europe.eu/wp-content/uploads/2018/05/FAQ_MDR_180117_V1.0-1.pdf

EU comission guidance:
https://ec.europa.eu/docsroom/documents/33862/attachments/1/translations/en/renditions/native

Irish authority:
https://www.hpra.ie/docs/default-source/publications-forms/guidance-documents/ia-g0004-guide-for-distributors-of-medical-devices-v1.pdf?sfvrsn=13

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Key take aways:

- You need to add or change way of working in several areas
- Logistics and warehouse
- Incoming inspections
- Traceability
- Promotion

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www.lowendahl.eu
peter@lowendahl.eu
Phone Int + 46 (0) 722-313355