# Medical Device Regulation

## T**raceability, registration of devices and of economic operators, summary of safety and clinical performance, Eudmed**

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# Identification within supply chain

- Distributors and importers shall co-operate with the manufacturer or AR to achieve appropriate level of traceability of devices
- Economic operators shall be able to identify the following to the CA, for period depending on device
  - any economic operator to whom they have directly supplied a device
  - any economic operator who has directly supplied them with a device
  - any health institution or healthcare professional to whom they have directly supplied a device

# Unique Device Identification system

- UDI comprises
  - a device identifier (‘DI’) specific to a manufacturer and a device , providing access to the information laid down in Part B of Annex V
  - production identifier (‘PI’) that identifies the produced device's unit and if applicable the packaged devices as specified in Annex V Part C
- Application of the UDI on the label of the device or on its package
- Storage of the UDI by the economic operators, the health institutions and the healthcare professionals
- Establishment of electronic system on UDI (‘UDI database’)

# Device identifier (‘DI’)

- Quantity per package configuration
- Basic UDI-DI according to article 29 and additional identifier(s)
- How the device production is controlled (expiration date or manufacturing date, lot or batch number, serialisation number)
- Unit of use device identifier (when a UDI is not assigned to the device at the level of its unit of use, a 'unit of use' device identifier shall be assigned to associate the use of a device with a patient)
- Name and address of the manufacturer (as indicated on the label)
- Single registration number according to article 31 (2)
- Name and address of the AR (as indicated on the label)
- Medical Device Nomenclature code according to article 26
- Risk class of the device
- Trade/brand name
- Device model, reference, or catalogue number
- Clinical size (including volume, length, gauge, diameter)

# Device identifier (‘DI’)

- Storage and/or handling conditions (as indicated on the label or in the instructions for use)
- Additional trade names of the device
- Labelled as single use device (y/n)
- Restricted number of reuses
- Device packaged sterile (y/n)
- Need for sterilisation before use (y/n)
- Labelled as containing latex (y/n)
- Labelled in accordance with Annex I, section 10.4.5
- URL for additional information, e.g. electronic instructions for use (optional)
- Critical warnings or contraindications
- Status of the device on the market (choice box, no longer placed on the market, recalled, Field Safety Corrective Action initiated)

# production identifier (‘PI’)

- The Production Identifier is a numeric or alphanumeric code that identifies the unit of device production
- The different types of Production Identifier(s) include
  - serial number
  - lot/batch number
  - Software identification
  - Manufacturing and/or expiration date

# UDI

- Before placing a device on the market, the manufacturer shall assign to the device and to all higher levels of packaging a UDI
- UDI carrier shall be placed on device label  and on higher level packaging
- UDI shall be used for reporting serious incidents/field safety corrective action
- Basic UDI device identifier of device appear on EU declaration of conformity
- The manufacturer shall keep up-to-date a list of all applied UDI as part of the technical documentation
- Economic operators shall store and keep UDI of the devices which they have supplied or they have been supplied with, if they belong to
  - class III implantable devices
  - the devices, categories or groups of devices determined by a special measure
- Health institutions shall store/keep UDI of devices which they have supplied or they have been supplied for class III implantable devices
- For devices other than class III implantable devices, MS shall encourage, and may require, health institutions to store/keep UDI of devices

# Process for registration of devices

- The manufacturer shall, in compliance with the rules of the designated issuing entities, assign a Basic UDI-DI
- Responsible natural or legal person shall assign to the system or procedure pack a Basic UDI-DI and submit to the UDI database this Basic UDI-DI and the linked information
- Where a manufacturer of a device applies a conformity assessment procedure, manufacturer shall submit to UDI database Basic UDI-DI and the linked information before placing the device on market
- Manufacturer shall assign the Basic UDI-DI to the device before applying for a conformity assessment procedure by NB
- The Notified Body shall reference the Basic UDI-DI on the certificate issued and enter the required information
- After the issuing of the relevant certificate and before placing the device on the market the manufacturer shall submit to UDI database the linked information
- Before placing a device on market, manufacturer shall submit to Eudamed database information referred to section 2 of part A of annex VI, with the exception of its section 2.2, and keep it updated

# Electronic system on registration of economic operators

- The Commission shall set up and manage an electronic system
  - to create the single registration number
  - to collate and process information that is necessary and proportionate to identify manufacturer, AR and importer
- Within two weeks after placing device on the market, importers shall verify that manufacturer or AR has uploaded to electronic system
  - economic operator's role (manufacturer, AR or importer)
  - name, address and contact details of the economic operator
  - where submission of information is completed by another person on behalf of any of the economic operators the name, address and contact details of this person
  - name address and contact details of the person responsible for regulatory compliance according to Article 15
- Importers
  - shall inform relevant AR or manufacturer if the information is not included or is incorrect
  - shall add his details to the relevant entry/entries

# Process for registration of manufacturers, authorised representatives and importers, single registration number

- Manufacturers, AR and importers, shall submit to electronic system required information before placing device on market. In cases where the conformity assessment procedure requires the involvement of a NB the information shall be submitted to the electronic system before applying to a NB
- After having verified data entered, CA shall procure from electronic system single registration number (SRN) and issue to manufacturer, AR or importer
- The manufacturer shall use SRN when applying to NB for certification and for entering the electronic system on UDI
- Within one week of any change occurring in relation to the information referred to in paragraph 1, the relevant economic operator shall update the data in the electronic system
- Not later than one year after submission of the information in accordance with paragraph 1, and then every second year thereafter, economic operator shall confirm the accuracy of the data. CA shall verify the confirmed data. If failure to confirm within six months of the due date, MS may take appropriate corrective measures
- Data contained in the electronic system shall be accessible to the public.
- CA may use the data to administer a fee to manufacturer, AR or importer

# Summary of safety and clinical performance

- Summary of safety and clinical performance required for class III and implantable devices
  - clear to the intended user and the patient
  - be made available to the public via Eudamed
- Draft of this summary shall be part of the documentation to be submitted to NB and validated
- After validation the notified body shall upload this summary report to Eudamed
- The manufacturer shall mention on the label or instructions for use where the summary report is available

# Summary of safety and clinical performance

- Identification of the device and the manufacturer, including the basic UDI-DI and the single registration number
- The intended purpose of the device, including indications, contra-indications and target populations
- A description of the device
  - reference to previous generation(s) or variants, and description of the differences
  - description of accessories, other medical devices and other products that are not MD, which are intended to be used in combination with the MD
- Possible diagnostic or therapeutic alternatives
- Reference to harmonized standards and common specifications
- Summary of clinical evaluation as referred to in annex XIII, and relevant information on post market clinical follow up
- Suggested profile and training for users
- Information on residual risks, undesirable effects, warnings and precautions

# European databank on medical devices

- Enable the public to be adequately informed about
  - devices placed on the market
  - corresponding certificates issued by notified bodies
  - relevant economic operators
- Enable unique identification and to facilitate traceability of devices
- Enable the public to be adequately informed about clinical investigations
- Enable sponsors of clinical investigations to comply with obligations
- Enable manufacturers to comply with information obligations
- Enable the CA and the Commission to carry out their tasks relating to this Regulation on a well informed basis and to enhance the cooperation between them

# European databank on medical devices

- Electronic system on registration of devices referred to in Article 29(4)
- Electronic system on UDI referred to in Article 28
- Electronic system on registration of economic operators referred to in Article 30
- Electronic system on notified bodies and on certificates referred to in Article 57
- Electronic system on clinical investigations referred to in Article 73
- Electronic system on vigilance and post-market surveillance referred to in Article 92
- Electronic system on market surveillance referred to in Article 100

# European databank on medical devices

- The data shall be entered into Eudamed by the Member States, NB, economic operators and sponsors
- The Commission shall provide for technical and administrative support to users of Eudamed
- Information collated and processed by Eudamed shall be accessible to the Member States and to the Commission
- Information shall be accessible to NB, economic operators, sponsors and the public
- Public parts of Eudamed are presented in an user-friendly and easily-searchable format