Medical Device Regulation
Economic Operators

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Economic operators

- Economic operators
  - manufacturer, authorised representative, importer and distributor
- Manufacturer
  - natural or legal person who manufactures or fully refurbishes a device
  - has a device designed, manufactured or fully refurbished, and markets that device under his name or trademark
- Importer
  - any natural or legal person established within the Union who places a device from a third country on the Union market
- Distributor
  - any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a device available on the market
- Inclusion of diagnostic services and internet sales

General obligations of manufacturer

- Design and manufacture devices in accordance with the regulation
- Establish, execute, maintain and document a system
  - for risk management
- Conduct a clinical evaluation
- Conduct post market clinical follow-up
- Draw up and keep up to date technical documentation
  - allow assessment of the conformity
- Complete an appropriate conformity assessment
- Prepare a declaration of conformity
- Comply with the obligations related to the UDI system

General obligations of manufacturer

- Make technical documentation, EU declaration of conformity available to CA (STED)
- Ensure that procedures are in place to keep series production in conformity
  - Change product design or characteristics according to changes in the harmonised standards or CS
- Operate a quality management system and maintain product conformity
- Where manufacturers have their devices designed and manufactured by another legal or natural person
  - information on the identity of that person shall be part of the information to be submitted in accordance with Article 25
- Supply instructions for use in a MS language
- Procedures for devices that do not comply – including vigilance
- Identify suppliers conducting device design & manufacture

Quality management system

- Consists of all parts and components of a manufacturer’s organisation
  - dealing with the quality of processes, procedures and devices
- Manage the structure, responsibilities, procedures, processes and management resources
  - implement the needed principles and actions to achieve compliance
- Strategy for regulatory compliance
  - compliance with conformity assessment procedures
  - management of modifications to devices covered by the system

Quality management system

- Identification of applicable general safety and performance requirements
  - exploration of options to address these requirements
- Responsibility of the management
- Resource management
  - selection and control of suppliers and sub-contractors
- Risk management
- Clinical evaluation and post-market clinical follow-up
- Product realisation
  - planning, design, development, production and service provision
- Control of the UDI-Code assignments to all relevant devices
  - ensuring consistency of information provided

Quality management system

- Setting-up, implementation and maintenance
  - systematic post-market surveillance system
- Handling communication with
  - competent authorities, notified bodies
  - other economic operators, customers and/or other stakeholders
- Processes
  - reporting of serious incidents and field safety corrective actions in the context of vigilance
  - monitoring and measurement of output, data analysis and product improvement
- Management of corrective and preventive actions and verification of their effectiveness

Device information

- Each device shall be accompanied by the information needed to identify the device and its manufacturer
- Communicate safety and performance related information to the user, or other person, such information may appear
  - on the device itself
  - on the packaging
  - in the instructions for use
  - on company website
- In an official Union language(s) determined by the Member State where the device is available
- The particulars on the label shall be indelible, easily legible, clearly comprehensible to the intended user or patient

Non conformity of device

- Immediately take the necessary corrective action
  - bring that product into conformity
- Withdraw it or recall it, as appropriate
- Inform the distributors, AR and the importers accordingly
- Where the device presents a serious risk
  - immediately inform the CA of MS and NB any corrective action taken
- System for recording and reporting of incidents and field safety corrective actions
- Manufacturers shall provide CA with information and documentation necessary to demonstrate the conformity of device
  - in an official Union language determined by the Member State
  - CA may require that the manufacturer provide samples of the device free of charge or grant access to the device
  - Manufacturers shall cooperate with a CA, any corrective action taken to eliminate or mitigate the risks posed by devices

Non conformity of device

- If the manufacturer fails to cooperate or the information and documentation provided is incomplete or incorrect, CA may take appropriate measures to
  - prohibit or restrict the device’s being made available on their national market
  - withdraw the device from that market or recall
- If a device has caused damage, CA shall, upon request, facilitate the provision, of the information and documentation to
  - the potentially injured patient or user and, as appropriate
  - the patient's or user's successor in title
  - the patient's or user's health insurance company
  - other third parties affected by damage caused to patient or user

Compensation and liability

- Natural or legal persons may claim compensation for damage caused by a defective device
  - in accordance with applicable Union and national law
- Manufacturers shall have measures in place to provide sufficient **financial coverage**
  - in respect of their **potential liability** under Directive 85/374/EEC
  - without prejudice to more protective measures under national law

Authorised representative

- Where the manufacturer of a device is not established in any Member State
  - the device may only be placed on the Union market if the manufacturer designates a single **authorised representative**
- The designation shall constitute the authorised representative's mandate
  - valid only when accepted in writing by the authorised representative
  - effective at least for all devices of the same generic device group
- The authorised representative shall provide a copy of the mandate to the competent authority, upon request

AR mandate

- Verify
  - EU declaration of conformity and technical documentation have been drawn up
  - appropriate conformity assessment procedure has been carried out by the manufacturer
- Keep available a copy of the technical documentation, the EU declaration of conformity, a copy of relevant certificate
  - including any amendments and supplements at the disposal of CA for the period referred to in Article 10(8)
- Comply with the registration obligations laid down in Article 31
- Verify that manufacturer has complied with the registration obligations laid down in Article 27 and 29
- In response to a request from a CA
  - provide that CA with all the information and documentation necessary to demonstrate the conformity of a device
  - in an official Union language determined by the MS

AR mandate

- Forward to the manufacturer any request by a CA for samples, or access to a device and verify that CA receives the samples or gets access to the device
- Cooperate with the CA on any preventive or corrective action taken to eliminate or mitigate the risks posed by devices
- Immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device
- Terminate the mandate if the manufacturer acts contrary to his obligations under this Regulation.
- **AR shall be legally liable for defective devices on the same basis as, jointly and severally, with the manufacturer**
- AR who terminates the mandate shall immediately inform CA of MS, NB of termination of mandate and reasons therefore

Change of AR

- Determine the date of termination of the mandate with the outgoing AR and date of beginning of the mandate with the incoming AR
- The date until which the outgoing AR may be indicated in the information supplied by the manufacturer, including any promotional material
- Transfer documents, including confidentiality aspects and property rights
- Obligation of the outgoing AR after the end of the mandate to forward to the manufacturer or incoming AR any complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device for which he had been designated as AR

Person responsible for regulatory compliance

- At least one qualified person possessing expert knowledge in the field of MD in **manufacturer or AR**'s organisation
  - a degree or equivalent in law, medicine, pharmacy, engineering or another relevant scientific discipline plus at least one year of professional experience in regulatory affairs or in QMS in MD or
  - four years of professional experience in regulatory affairs or QMS relating to MD
- Responsible for ensuring
  - conformity of devices is appropriately assessed before a batch is released
  - technical documentation and declaration of conformity are drawn up and updated
  - vigilance requirements have been fulfilled
  - subjects in clinical investigations or performance evaluation for interventional studies
- Qualified person should suffer no disadvantage by performing their duties
- Micro and small enterprises are not required to have the person within their organisation but shall have such person permanently and continuously at their disposal

General obligations of importers

- Verify
  - device has been CE marked and that the declaration of conformity of the device has been drawn up
  - a manufacturer is identified and, that an AR has been designated by the manufacturer
  - the device is labelled in accordance with this Regulation and accompanied by the required instructions for use
  - UDI has been assigned by the manufacturer
- Not place the device on the market
  - If the device is not in conformity
- inform the competent authority
  - If the device presents a serious risk or is falsified

General obligations of importers

- Indicate their name, registered trade name or registered trade mark and the address of their registered place of business on the device or on its packaging or in a document accompanying the device
- Ensure that any additional label does not obscure any information on the label provided by the manufacturer
- Verify that the device is registered in the electronic system. Importers shall add their details to the registration
- Ensure storage or transport conditions do not jeopardise its compliance with the general safety and performance requirements and shall comply with the conditions set by the manufacturer
- Keep a register of complaints, of non-conforming products and of product recalls and withdrawals, and provide the manufacturer, AR and distributors with any information requested by them to allow them to investigate complaints
- If a device is not in conformity, importers shall immediately inform the manufacturer and his AR

General obligations of importers

- Importers shall co-operate with the manufacturer, AR and CA
  - to ensure that the necessary corrective action to bring that device into conformity, withdraw or recall it is taken
  - where the device presents a serious risk
    - immediately inform the CA and NB
    - give details of the non-compliance and of any corrective action taken
- Importers who have received complaints or reports from healthcare professionals, patients or users about suspected incidents shall immediately forward this information to the manufacturer and AR
- Importers shall keep a copy of the EU declaration of conformity and a copy of the relevant certificate including any amendments and supplements
- Importers shall cooperate with CA
  - on any action taken to eliminate or mitigate risks posed by devices which they have placed on the market
  - shall provide samples of device free of charge or grant access

General obligations of distributors

- Verify
  - the device has been CE marked and that the declaration of conformity of the device has been drawn up
  - the product is accompanied by the information to be supplied by the manufacturer
  - for imported devices, the importer has complied with the requirements set out in Article 13(3)
  - UDI has been assigned by the manufacturer
- Distributor may apply a sampling method representative of products supplied by that distributor to verify
- Distributors shall ensure that storage or transport conditions comply with the conditions set by the manufacturer

General obligations of distributors

- Where a distributor considers a device is not in conformity he shall
  - not make the device available on the market until it has been brought into conformity
  - inform the manufacturer, AR, and importer
  - co-operate with the manufacturer and/CA, importer, and CA to ensure that the necessary corrective action to bring that device into conformity, withdraw or recall it
- Where the distributor considers the device presents a serious risk or is falsified
  - he shall also inform the CA
  - giving details, in particular, of the non-compliance and of any corrective action taken

General obligations of distributors

- Distributors who have received complaints or reports from healthcare professionals, patients or users about suspected incidents
  - shall immediately forward this information to the manufacturer, AR, importer
  - keep a register of complaints, of non-conforming products and of product recalls and withdrawals
  - keep the manufacturer, AR, importer informed of such monitoring and provide them with any information upon their request
- Distributors shall, in response to a request from a CA
  - provide it with all the information and documentation at its disposal and is necessary to demonstrate the conformity of device. This obligation shall be considered fulfilled when the AR provides the required information
  - cooperate with CA, on any action taken to eliminate the risks posed by devices
  - provide free samples of the device or grant access to the device

Cases in which obligations of manufacturers apply to importers, distributors or other persons

- A distributor, importer or other natural or legal person shall assume the obligations incumbent on manufacturers if he does any of the following:
  - makes available on the market a device under his name, registered trade name or registered trade mark, except in cases where a distributor or 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
  - 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
- shall not apply to any person who, while not considered a manufacturer, assembles or adapts a device already on the market to its **intended purpose** for an individual patient

Entity not regarded as manufacturer

- Provision, including translation, of the information supplied by manufacturer relating to device already marketed and of further information to market product
- Changes to the outer packaging of device already on the market, including change of pack size, if the repackaging is necessary to market product
- Indicate the activity carried out together with his name, trade name or trade mark and address on device or, on its packaging or in document with device
- Ensure a quality management system including procedures which ensure
  - the translation of information is accurate and up-to-date
  - the activities are performed by means and under conditions that preserve the original condition of device and packaging of repackaged device is not defective, of poor quality or untidy

Entity not regarded as manufacturer

- Part of the quality management system shall be procedures ensuring
  - distributor or importer is informed of any corrective action taken by manufacturer to respond to safety issues or to bring it in conformity
- At least 28 days prior to making relabelled or repackaged device available, distributor or importer
  - inform manufacturer and CA
  - provide them with a sample of the relabelled or repackaged device, including any translated label and instructions for use.
- Within the same 28 days, the entity
  - submit to the CA a certificate, issued by a NB
  - attest that the quality management system complies with the requirements

Single-use devices and reprocessing

- Reprocessing and further use of single-use devices may only take place where permitted by national law and only in accordance with MDR
- Any natural or legal person who reprocesses a single-use device to make it suitable for further use shall
  - be considered to be the manufacturer of the reprocessed device
  - assume the obligations incumbent on manufacturers, which include obligations related to identification traceability of the reprocessed device
- Only reprocessing of single-use devices that is considered safe according to the latest scientific evidence may be carried out

Single-use devices and reprocessing

- The name and address of reprosessor shall be indicated on
  - label
  - instructions for use of the reprocessed device
- The name and address of the manufacturer of the original single-use device shall no longer appear on the label
  - but shall be mentioned in instructions for use of reprocessed device
- MS that permits reprocessing of single-use devices may maintain or introduce stricter national provisions restricting or prohibiting, within its territory
  - reprocessing of single-use devices
  - transfer of single-use devices to another MS or to a third country with a view to their reprocessing
  - making available or further use of reprocessed single-use devices
- MS shall notify the Commission and other MS of the national provisions. The Commission shall keep the information publicly available

single-use devices that are reprocessed and used within a health institution

- MS may decide not to apply all rules relating to manufacturers' obligations provided that they ensure that
  - safety and performance of reprocessed device is equivalent to that of original device
- reprocessing is performed according to common specifications, detailing the requirements on
  - risk management, including the analysis of construction and material, related properties of device and procedures to detect changes in design of original product as well as of its planned application after reprocessing
  - validation of procedures for the entire process, including cleaning steps
  - product release and performance testing
  - quality management system
  - reporting of incidents involving devices that have been reprocessed
  - traceability of reprocessed devices.
- MS shall encourage, and may require, health institutions to provide information to patients on use of reprocessed devices

Implant card and information about implantable devices

- Manufacturers of implantable devices shall provide implant card for particular patients
  - information allowing the identification of the device, including the device name, serial number, batch code or lot number, the UDI, device model, name, address and the URL of the website of the manufacturer
  - manufacturer shall provide the information on a card delivered with the device
  - any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences, medical examinations or environmental conditions
  - information on expected life cycle and follow-up
  - any other information to assure a safe use of the device by patient
- Health institutions make the information available to the patients who have been implanted, together with the implant card, which shall bear their identity
- Exempted implants: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates wires, pins, clips and connectors

EU declaration of conformity

- The EU declaration of conformity shall state that fulfilment of the requirements specified in this Regulation has been demonstrated
  - It shall be continuously updated. The minimum content of the EU declaration of conformity is set out in Annex III
  - It shall be translated into an official Union language or languages required by the MS in which the device is made available
- Where, concerning aspects not covered by this Regulation, devices are subject to other Union legislation which also requires a declaration of conformity by the manufacturer that fulfilment of the requirements of that legislation has been demonstrated
  - a single EU declaration of conformity shall be drawn up in respect of all Union acts applicable to the device containing all information required for identification of the Union legislation to which the declaration relates
- By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for compliance with the requirements of this Regulation and all other Union legislation applicable to the device

CE marking of conformity

- Devices, other than custom-made or investigational devices, considered to be in conformity shall bear the CE marking of conformity
- The CE marking shall be affixed
  - visibly, legibly and indelibly to the device or its sterile pack
  - on the packaging if necessary
  - in the instructions for use and on the sales packaging
  - before the device is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use
- CE marking shall be followed by the identification number of NB. The identification number shall also be indicated in any promotional material which mentions that a device fulfils the legal requirements for CE marking
- Where devices are subject to other Union legislation concerning other aspects which also provide for the affixing of the CE marking, the CE marking shall indicate that the devices also fulfil the provisions of the other legislation

Systems and procedure packs

- Verify mutual compatibility of the devices and, if applicable other products
  - in accordance with the manufacturers' instructions and has carried out his operations in accordance with those instructions
- Package the system or procedure pack and supplied relevant information to users incorporating the information to be supplied by the manufacturers of the devices or other products which have been put together
- Activity of putting devices and other products together as a system or procedure pack is subject to appropriate methods of internal monitoring, verification and validation

Parts and Components

- Parts or components
  - intended to replace parts or components that are defective or worn to maintain or re-establish performance of a device
- Responsibility to determine the part or component does not adversely affect the safety and performance of the device
  - supporting evidence available to CA
  - for implantable devices must cooperate with the manufacturer of the device
- Part or component that significantly changes the performance or safety characteristics of a device
  - shall be considered a device in its own right