In-House Medical Devices in Europe

MDR Article 5

5. With the exception of the relevant general safety and performance requirements set out in Annex I, the requirements of this Regulation shall not apply to devices, manufactured and used only within health institutions established in the Union, provided that all of the following conditions are met:

(a) the devices are not transferred to another legal entity,

Examples:
- one hospital = one legal entity
- One hospital = several legal entities (different health institutions in one hospital)
- Several hospitals = one legal entity (part of one health institution)

(b) manufacture and use of the devices occur under appropriate quality management systems,

- Conformity assessment: compliance with article 5 and declaration of fulfillment of GSPR
- Identification of applicable GSPR and documentation of solutions for fulfillment, applicable standards
- Responsibility of the management, resource management and supplier control
- Risk management
- System for product tracking
- Documented and controlled development and production as well as service
- Clinical evaluation and PMCF
- Review and data gathering of experience from the product life cycle and clinical use
- Communication with stake-holder (CA), CAPA System

(c) the health institution justifies in its documentation that the target patient group's specific needs cannot be met, or cannot be met at the appropriate level of performance by an equivalent device available on the market,

- Specific need: addresses the characteristics in article 2(1) MDR, specific performance characteristics, specific requirements on safety
- Target patient group: indication, contraindications, conditions to be treated
- Equivalency: technical, biological, clinical: documentation and rationale for non-equivalency based on scientific justification

(d) the health institution provides information upon request on the use of such devices to its competent authority, which shall include a justification of their manufacturing, modification and use;

- Review of justification on a regular basis
- Rationale for application of article 5: no alternative available in the market
- Research for available equivalent devices: planned, justified and documented (EUDAMED, Market Analysis)

(e) the health institution draws up a declaration which it shall make publicly available, including:

(i) the name and address of the manufacturing health institution;
(ii) the details necessary to identify the devices;
(iii) a declaration that the devices meet the general safety and performance requirements set out in Annex I to this Regulation and,
where applicable, information on which requirements are not fully met with a reasoned justification therefore,

- Recommendation (in case no national provisions are in place):
- Name of health institution
- Address and contact dates
- Contact date of the person responsible of safety and performance concerns
- Device information:
- Name, no. code
- Device type
- Risk class
- Intended purpose
- Applicable GSPR which are fulfilled
- Applicable GSPR which are not fulfilled with justification

(f) the health institution draws up documentation that makes it possible to have an understanding of the manufacturing facility, the manufacturing process, the design and performance data of the devices, including the intended purpose, and that is sufficiently detailed to enable the competent authority to ascertain that the general safety and performance requirements set out in Annex I to this Regulation are met;

- Description of the manufacturing site and environment: equipment, processes, qualification of personnel
- Raw materials, suppliers if applicable relevant service providers
- Mode of action, principle of operation, technical and performance specifications
- Chemical, physical, biological specification, system architecture
- Applied standards or common specifications
- Clinical performance, bench testing, analytical validation
- Intended purpose, indications, contra-indications, specification of devices which are used in combination

(g) the health institution takes all necessary measures to ensure that all devices are manufactured in accordance with the documentation referred to in point (f),

- Quality assurance procedures
- Documented manufacturing process

(h) the health institution reviews experience gained from clinical use of the devices and takes all necessary corrective actions.

- PMS Plan, if applicable PMCF Plan
- Trendreporting
- Vigilance process
- Documented CAPA process

Member States may require that such health institutions submit to the competent authority any further relevant information about such devices which have been manufactured and used on their territory. Member States shall retain the right to restrict the manufacture and the use of any specific type of such devices and shall be permitted access to inspect the activities of the health institutions.

- Data on use of the devices: number of products manufactured, number of products used
- Feedback from users and patients
- Comlaints and Data from CAPA system

This paragraph shall not apply to devices that are manufactured on an industrial scale.

- The manufacturing process is designed to produce only the for the health institution needed number of devices
- The manufacturing process is not designed for commercial purposes but can use methods which are state of the art in industrial manufacturing processes