General Safety and Performance Requirements

Under the EU's MDR, Annex I General Safety and Performance Requirements applies to all devices. These requirements are broad any some of them will apply to any given device.

There are 3 major chapters in Annex I:

- General requirements
- Requirements regarding design and manufacture
- Requirements regarding the information supplied with the device

General Requirements

Most of this chapter deals with risk management. The overarching principle is that devices are safe, effective, and not compromise clinical condition. Risks are:

- Acceptable when weighed against the benefits to the patient
- Compatible with a high level of health and safety protection consistent with the generally acknowledged state of the art

The manufacturer adopts a risk management system. It will probably use the yet to be published EN ISO 14971:2017, which Ombu anticipates will be harmonized to the MDR.

Risk reduction uses the priority order:

(a) Eliminate or reduce risks as far as possible through safe design and manufacture

(b) Where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated

(c) Provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users.

In eliminating or reducing risks related to use error:

(a) Reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety)

(b) Give consideration to the technical knowledge, experience, education, training, and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled, or other users).

Inform users of any residual risks.

Requirements Regarding Design and Manufacture

Chapter II is extensive and divided into the following subheadings:

- Chemical, physical, and biological properties
- Infection and microbial contamination
- Devices incorporating a substance considered to be a medicinal product and devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body

- Devices incorporating materials of biological origin
- Construction of devices and interaction with their environment
- Devices with a diagnostic or measuring function
- Protection against radiation
- Electronic programmable systems – devices that incorporate electronic programmable systems and software that are devices in themselves
- Active devices and devices connected to them
- Particular requirements for active implantable devices
- Protection against mechanical and thermal risks
- Protection against the risks posed to the patient or user by supplied energy or substances
- Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons

Requirements Regarding the Information Supplied With the Device
Chapter 3 covers the label and the instructions for use. It includes:
- Information on the label
- Information on the sterile packaging
- Information in the instructions for use

Common Specification
Common Specification (CS) means a set of technical and/or clinical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a device, process, or system.

Where:
- no harmonized standards exist or
- where relevant harmonized standards are not sufficient or
- where there is a need to address public health concerns

The Commission may adopt common specifications (CS) in respect of:
- the general safety and performance requirements set out in Annex I
- the technical documentation set out in Annexes II and III
- the clinical evaluation and post-market clinical follow-up set out in Annex XIV
- the requirements regarding clinical investigation set out in Annex XV

Harmonized Standards
Devices in conformity with the relevant harmonized standards or the relevant parts of those standards (published in the Official Journal) are presumed to in conformity with those requirements of this Regulation

The documentation shall contain demonstration of conformity with the general safety and performance requirements laid down in Annex I including the harmonized standards or CS applied or other solutions employed [Annex II, Section 4(c)]

Recommendations for Manufacturers
For each of your existing devices, determine which requirements from Annex I will apply

Determine which current harmonized standards would apply to those requirements

- Some of them you may already use
- Identify potential gaps

Remember that there are no Harmonized Standards for the new regulation
The Z-annexes will have to change, but the text of the standards probably will not

Remember that there are no Common Specifications for the new regulation

Start to compile the Technical Documentation required in Annex II Technical Documentation and Annex III Technical Documentation on Post-Market Surveillance