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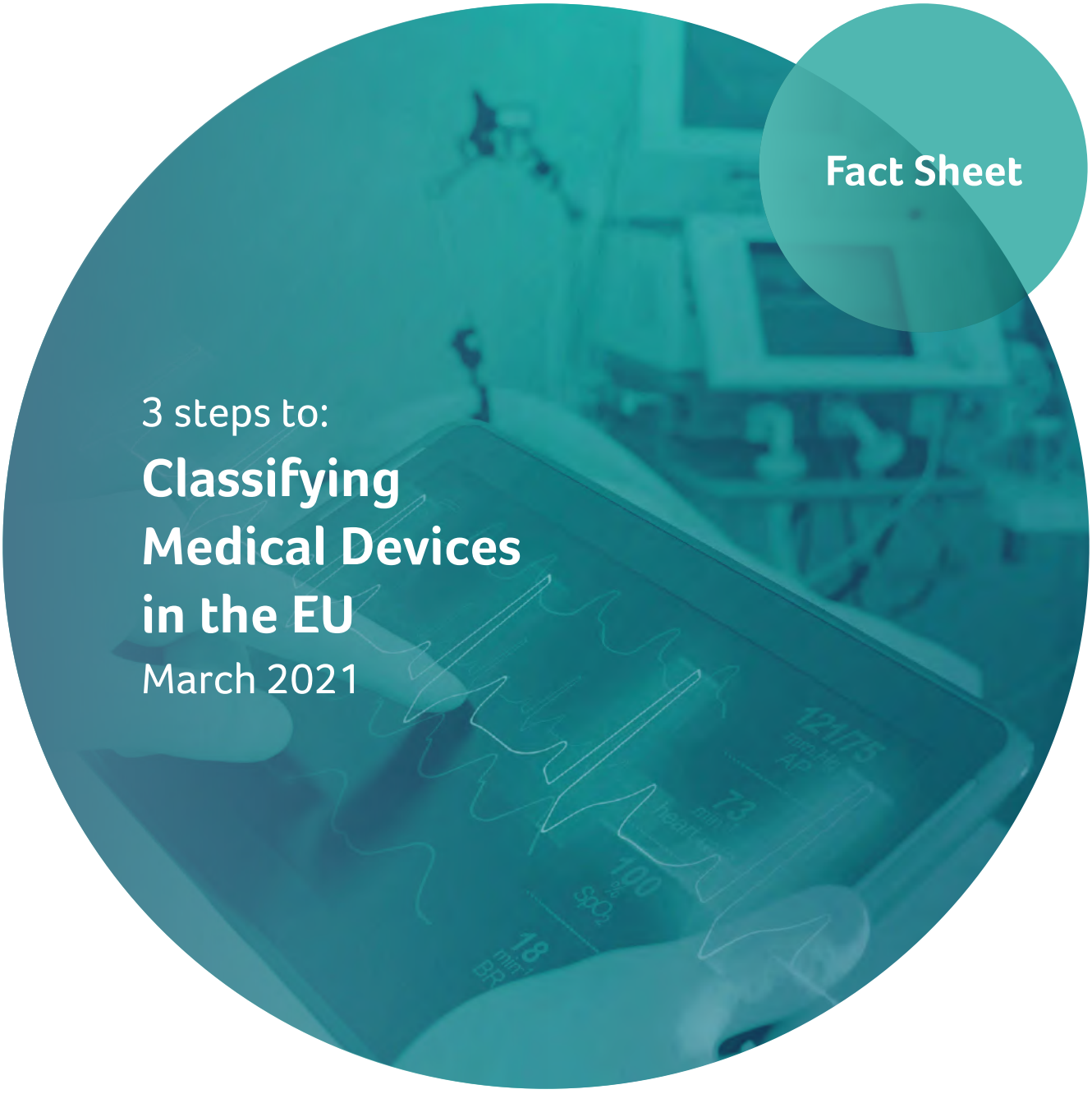

Fact Sheet

3 steps to:

Classifying Medical Devices in the EU

March 2021

Smart consulting,
enhanced medical solutions.

Classifying medical devices in the EU

STEP 1 | What's the intended use?

Define the intended use of your device to be marketed by your organisation

STEP 2 | Is your device a medical device?

Based on the intended use, the decision as to whether your product is a **medical device**, a **non-medical device** or an **accessory** must be made on the basis of the definitions of terms found in the EU directives, above all in the Medical Devices Regulation MDR 2017/745 according to Article 2:

'Medical device' covers:

"any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:"

- Diagnosis / prevention / monitoring / prediction / prognosis / treatment / alleviation of disease
- Diagnosis / monitoring / treatment / alleviation of / compensation for an injury or disability
- Investigation / replacement / modification of the anatomy, or of a physiological or pathological process or state
- Providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means

The following products are also considered as medical devices:

- Devices for the control or support of **conception**
- Products specifically intended for the **cleaning, disinfection or sterilisation** of devices as referred to above

Helpful Guidance Documents (MDD 93/42 related)

- Manual on Borderline & Classification in the Community Regulatory Framework for Medical Devices
- Definitions of "medical devices", "accessory" and "manufacturer" - MEDDEV 2.1/1
- Classification of Medical Devices - MEDDEV 2.4/1 rev.9

Classifying medical devices in the EU

STEP 3 | Classifying categories

The EU MDR 2017/745 has **4 main categories** for Medical Devices classification defined in Chapter V Section 1 Article 51:

Class I (includes the below sub classes)	Class IIa	Class IIb	Class III
Class Is | Class I product that is delivered sterile Class Im | Class I product with a measuring function Class Ir | Class I products that are reprocessed			

Low risk → **High risk**

If your device is a medical device according to the definition given in Step 2, define the classification of your device according to Annex VIII of the Medical Devices Regulation MDR 2017/745, which defines the following rules:

Rule 1	Non-invasive devices
Rule 2	Non-invasive devices intended for channelling or storing (which includes cells)
Rule 3	Non-invasive devices that modify biological or chemical composition of blood, body liquids, other liquids and cells
Rule 4	Non-invasive devices in contact with injured skin or mucous membrane
Rule 5	Devices invasive in body orifices
Rule 6	Surgically invasive devices for transient use
Rule 7	Surgically invasive devices for short term use
Rule 8	Surgically invasive devices for long term use and implantable (including any device administering medicinal products, surgical mesh or spinal disc)
Rule 9	Active therapeutic devices intended to exchange or administer energy
Rule 10	Active devices for diagnosis & monitoring, emit ionizing radiation
Rule 11	Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes (from Class I to Class III)
Rule 12	Active devices intended to administer and/or remove medicinal products, body liquids or other substances
Rule 13	All other active devices
Rule 14	Devices incorporating a medicinal substance including human blood or plasma
Rule 15	Contraception or prevention of the transmission of sexually transmitted diseases
Rule 16	Specific disinfecting, cleaning and rinsing devices
Rule 17	Devices specifically intended for recording of diagnostic images generated by X-ray radiation
Rule 18	Devices utilising non-viable tissues or cells of human origin or tissues of animal or derivatives
Rule 19	Devices incorporating or consisting of nanomaterial
Rule 20	Invasive devices with respect to body orifices to administer medicinal products by inhalation
Rule 21	Substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed
Rule 22	Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management