MEDICAL DEVICE CLASSIFICATION

After reading this Fact Sheet you should:

- Have a basic knowledge of medical device classification systems in EU and US.
- Understand how device classification impacts on the regulatory pathway.
- Have links to related resources.

Medical device innovators should determine their device classification from the outset, as it will inform the correct regulatory pathway per market and also determine requirements for the product development phases.

What regulations apply?

- In the EU, device classification is dealt with in Annex VIII of Regulations **EU MDR 2017/745 (Medical Devices)** and **EU IVDR 2017/746 (In Vitro Diagnostics)**. Updates and publications can be found **HERE**.
- In the USA, medical device and radiation-emitting product regulations are in the Code of Federal Regulations **Title 21 CFR Parts 800-1299**, which covers various aspects of design, clinical evaluation, manufacturing, packaging, labelling and post market surveillance.

What are 'Intended Use' and 'Indication for Use'?

Irrespective of different classification systems in force per country or region (EU), devices are generally 'classed' according to their intended purpose and the inherent risks they pose to patients and users. Before determining device classification, you should articulate the 'Intended Use' and 'Indications for Use' for your device. This also allows defining user needs, design inputs, and other design and development activities. Intended Use is the general purpose of the medical device or its function, i.e., what you "claim" the medical device does. Indications for Use describe the disease or condition the medical device will diagnose, treat, prevent, cure, or mitigate, including a description of the target patient population. Refer Article 2 – Definitions, of **EU MDR 2017/745 (Medical Devices)** for aspects to consider regarding Intended Use.

How are devices classified in the EU?

Medical device classification is rules-based and simple to follow: There are 22 rules that guide your device's classification (Annex VIII of **EU MDR 2017/745**), which are each to be considered alongside the device's duration for use.

Chapter V Section 1 Article 51 of **EU MDR 2017/745** details the four main categories for medical device classification. (Article 52 deals with conformity assessment).

- Class I (lowest risk)
  - Class Is: Class I product delivered sterile;
  - Class Im: Class I product with a measuring function
  - Class Ir: Class I products that are reprocessed
- Class IIa
- Class IIb
- Class III (highest risk)

For Classes Is/Im/Ir/II/III a notified body is required for certification of the specific sub-class aspect.

For *in-vitro* diagnostic devices a 7-rules system applies. Chapter V Section 1 Article 47 of **EU IVDR 2017/746** outlines the in vitro device classification. (Article 48 deals with conformity assessment).

- Class A (lowest risk)
- Class B
- Class C
- Class D (highest risk)

Classes B/C/D will require assessment and certification by a notified body for medical devices (appropriately designated for IVDs).

If your software is intended to be used for one or more medical purposes and performs these without being part of a hardware medical device, it is most likely Medical Device Software (MDSW) or *In Vitro* Diagnostic Software (IVDSW). The **Medical Device Coordination Group** published a good resource to help with classification.

Take note of '**special cases**', if applicable, such as: combination products, medical devices with an ancillary medicinal substance, companion diagnostics, medical devices made of substances that are systemically absorbed, and borderline products (**Medical Device Borderline Manual** of the EU Commission)

How are devices classified in the US?

The process of determining **device classification for the USA market** involves a different approach versus the EU, but the FDA provides clear instructions including a **useful video**. Classification is directly related to the Intended Use and Indications for Use of the device. The FDA has established classifications for approximately 1,700 different generic types of devices and grouped them into **16 medical specialties** referred to as panels. All devices within the **database** are assigned to one of three regulatory classes based on the level of 'control' necessary to assure the safety and effectiveness of the device. Therefore, you can look for devices similar to yours and determine its classification this way. Also, you will be able to determine the regulatory control requirements for your device. '**General Controls**' apply to all medical devices (unless exempted by regulations), '**Special Controls**' are added for Class II devices, and Class III devices require General Controls and **Pre-market Approval** (PMA).

The three classes and the requirements which apply to them are:

- Class I (low to moderate risk)
  General Controls
  - With Exemptions
  - Without Exemptions
- Class II (moderate to high risk)
  General Controls and Special Controls
  - With Exemptions
  - Without Exemptions
- Class III (high risk)
  General Controls and Premarket Approval

What is a Regulatory Pathway?

Once you have decided your device classification per the EU and/or US, you will know what your 'pathway' to market is:

EU: Your device's classification determines the **conformity assessment** requirements. Therefore, depending on the device classification, one of the following would apply:

- Self-declare & registration: Typical for Class I: non-sterile, non-measuring, non-reprocessed
- 3rd party audit (by an accredited notified body organisation):
  - Class Is/Im/Ir: Sterility / measurement / re-usability.
  - Class IIa/IIb/III: ISO13485 QMS & Technical documentation (safety & performance data; clinical data to support safety & efficacy).

USA: Broadly speaking your path to market is most commonly one of:

- Class I/II exempted products: Many Class I and certain Class II devices are exempt from the pre-market notification (PMN) and/or the quality system (QS) regulation.
- Class I/II non-exempted products: Generally, a pre-marketing notification (PMN), known as a 510(K) is used for moderate-risk devices not exempted from pre-market review. Substantial equivalence with a predicate device must be shown; either a previously cleared Class I/II device not requiring a pre-market approval (PMA), or a pre-amendment Class III for which the FDA has not issued regulations requiring a PMA. Because novel devices lacking a legally marketed predicate are automatically designated Class III, the FDA introduced the De Novo route, an expedited mechanism for reclassifying these devices based on risk. Although requiring more data than a traditional 510(k), DE Novo often requires less information than a PMA application.
- Class III PMA: This is a stringent route for new or high-risk devices that require some clinical data before an approval decision.

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