# EU REGULATORY FRAMEWORK FOR MEDICAL DEVICES

PRE-market

## CLASSIFICATION OF MEDICAL DEVICES (MD):

Manufacturer determines the CLASSIFICATION of his MD based on Annex IX of MDD and related guidelines (Meddev)

| Class I (low risk) | Class IIa (low/medium risk) | Class IIb (medium/high risk) | Class III (high risk) |
|---|---|---|---|

**Conformity assessment procedure (art. 11)**

**'Technical documentation' (TD):** to be created by the manufacturer. It demonstrates the **safety and performance** of the device by proving that all 'Essential Requirements' laid down in the MDD are met (Annex I and includes a clinical evaluation (Annex X) and a risk assessment . All are based on clinical data.

**'Quality Assurance System' (QAS):** to be set up by the manufacturer. Ensures that each individual device fully meets the standards defined in the technical documentation. Achieved through clearly defined procedures for every step of the manufacturing process, from design phase to final inspection (Annex II or V).

**Notified Body (NB) audit:** NB assesses the TD and the QAS through an on-site inspection of the manufacturing premises, which takes 2-5 days. NB issues a Conformity Assessment 'Certificate' (Annex II 3.3. or Annex V 3.3.)

Manufacturer's **self-assessment** of his device*

**Pre-market approval for class III:** Manufacturer submits TD as a 'Design dossier' to the NB. NB assesses it and issues a **'Design-examination Certificate'** (Annex II or III)

**Declaration of conformity and CE marking**

Manufacturer issues a declaration of conformity stating that each device is in compliance with the all applicable Directives and affixes the CE **marking**

POST-market

Manufacturer **must keep TD and QAS updated and adapt** according to all gained post-market experience . NB regularly audits both, typically once per year (Annex II, paragraph 3.1)

**Surveillance system (preventive):**

**Market Surveillance:** done by **national Competent Authorities.** They monitor all devices on the market, i.e. through audits, product samples, complaints (Article 2).

**Post-market surveillance system (PMS):** to be set up by the manufacturer in order to collect, review and assess all information gained on a device in the post-market phase. The PMS is an integrated part of the 'quality assurance system' and regularly audited by a NB (Annex II, paragraph 3.1).

**Vigilance system (in case of incidents):**

a) **Manufacturer** is obliged to REPORT any incident related to his devices to the Competent Authority (Article10 and Annex II, paragraph 3.1)
b) A **Member State** may decide to **WITHDRAW**, **RESTRICT** or **PROHIBIT** the marketing of the device (Safeguard Clause, Art. 8)

* For devices with measuring function or which are sold sterile there is an intervention from the Notified Body

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