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From diagnostics to AI. How medical devices are structured?

A short guide based on the MDR & FDA overview.

Why does it matter?

Medical devices are not one category.

They differ in:

- Risk level.
- Purpose.
- Technology.
- Use environment.

Understanding this = better product, regulation, and market fit.

Risk level

Medical Device Regulation

Under EU MDR 2017/745, medical devices are classified into four risk classes:

- I (low)
- IIa (medium)
- IIb (medium-high)
- III (high)

Key classification factors:

- Invasiveness: Whether the device enters the body via orifices or surgical intervention.
- Duration: Transient (min), short-term (up to 30 days), or long-term (more than 30 days).
- Active vs. Non-Active: Active devices (using energy sources) have stricter rules (e.g., Rule 11 for software).

Food & Drug Administration

The FDA classifies medical devices into three categories:

- I (low)
- II (medium)
- III (high)

Key regulatory factors

- General controls: The baseline requirements for all devices, including facility registration, device listing, and quality systems.
- Special controls: These can include performance standards, postmarket surveillance, and specific labeling requirements.
- De Novo Process: A pathway for new, low-to-moderate risk devices that have no predicate, allowing them to be classified into Class I or II instead of the Class III.

Purpose

Diagnostic devices

Detect & monitor health.
Examples:

- MRI, ultrasound.
- Glucose meters.
- Imaging systems.

Foundation of clinical decision-making.

Therapeutic devices

Treat or manage conditions.
Examples:

- Infusion pumps.
- Dialisis systems.
- Rehabilitation devices.

Direct impact on patients outcomes.

Life-supporting devices

Keep patients alive.
Examples:

- Ventilators
- Defibrillators
- Heart-lung machines

Highest clinical criticallity.

Laboratory devices (IVD)

Enable diagnosis through samples. Examples:

- PCR systems
- Blood analyzers
- Rapid diagnostic tests

Backbone of modern diagnostics.

Technology

Active devices

Require internal or external power source. Examples:

- Implantable pacemakers.
- Glucose meters.
- Infusion pumps.

Acts by converting energy to function.

Passive devices

Physical, gravity, or bodily function. Examples:

- Bandages.
- Orthosis.
- Surgical instruments.

Can be consumable or implantable.

Software as a medical device

Calculations, analysis, or diagnostic. Examples:

- DTx.
- Cardiac monitoring.
- Computer-aided detection.

EHRs or wellness apps are not SaMDs.

Software in a medical device

Running and controlling hardware. Examples:

- Surgical robots.
- Imaging equipment.
- Implantable devices.

SiMD requires adherence to regulatory guidelines like SaMD.

Use environment

Hospital

Designed particularly for trained physicians.
Examples:

- X-ray machines.
- Surgical instruments.
- Catheters.

2 million types existing to support patients.

Point of care

Designed for speed, convenience and efficiency.
Examples:

- Glucose meters.
- Handheld ECG.
- Blood pressure monitors.

Easing the burden on healthcare systems.

Home

To manage & monitor health, or aid patients at home.
Examples:

- Pulse oximeteres.
- Respiratory devices.
- Wheelchairs, crutches.

Facilitating independent living or recovery.

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Save for later!