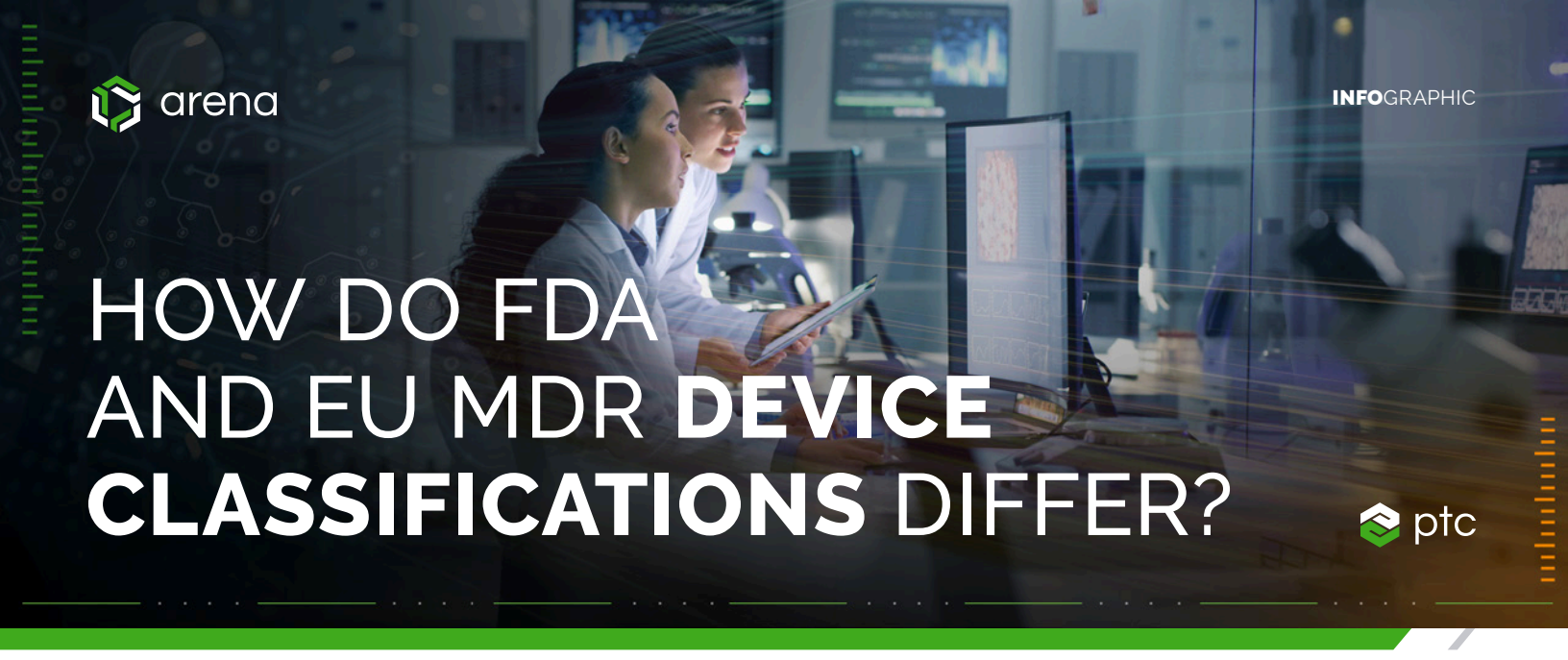

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INFOGRAPHIC

HOW DO FDA AND EU MDR **DEVICE CLASSIFICATIONS** DIFFER?

ptc

FDA

EU-MDR

CLASS III

*Examples: Defibrillators, Pacemakers, Prosthetic Heart Valves**

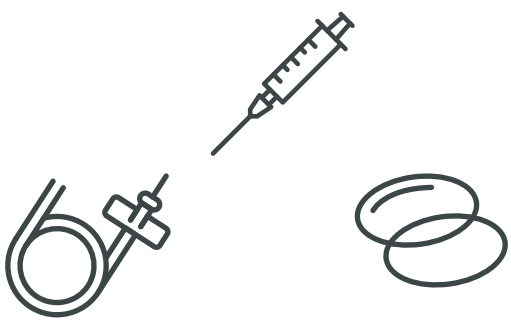
Risk Assessment: High

**Devices are Class III under FDA and EU MDR.*

CLASS II

FDA

Examples: Catheters, Syringes, Contact Lenses



Risk Assessment: Medium

EU MDR

IIb

Examples: Infusion Pumps, Ventilators, Dialysis Machines

Risk Assessment: Medium to High

IIa

Examples: Catheters, Hearing Aids, Diagnostic Equipment

Risk Assessment: Medium

CLASS I

FDA

Examples: Bandages, Stethoscopes, Wheelchairs

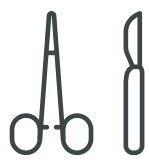
Risk Assessment: Low

EU MDR

Ir (Reusable)

Examples: Surgical Instruments, Endoscopes

Risk Assessment: Low



Im (Measuring)

Examples: Stethoscopes, Thermometers

Risk Assessment: Low

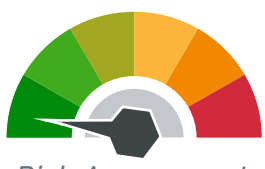
Is (Sterile)

Examples: Sterile Gauze, Personal Protection Kits

Risk Assessment: Low

I (Non-Sterile)

Examples: Wheelchairs, Hospital Beds



Risk Assessment: Low

CLASSIFICATION CRITERIA

FDA

510(k), premarket approval (PMA), and other regulatory controls are assigned to each device classification based on the following:

- Intended use
- Indications for use
- Risk level

EU MDR

22 classification rules are applied according to the following device categories:

- Noninvasive (Rules 1-4)
- Invasive (Rules 5-8)
- Active (Rules 9-13)
- Special rules (14-22)

See how Arena QMS can help you maintain device classification information and streamline compliance.

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