

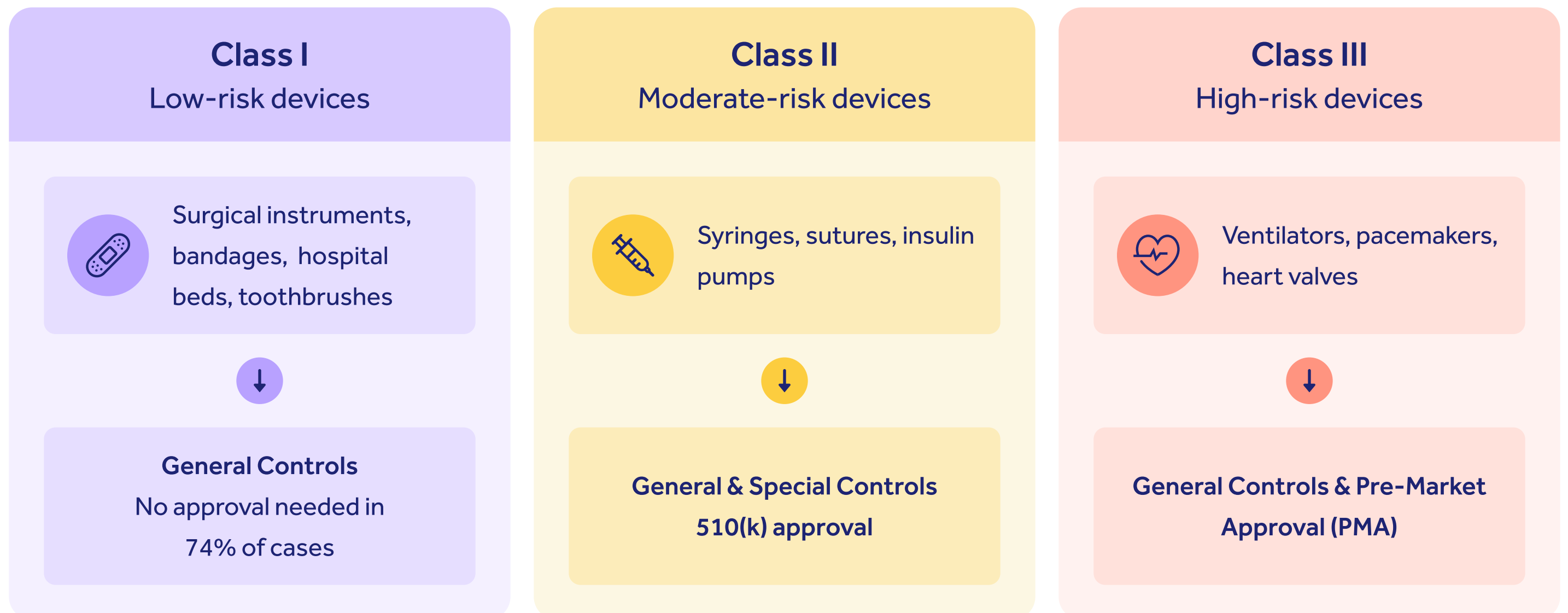


# Medical device classification guide

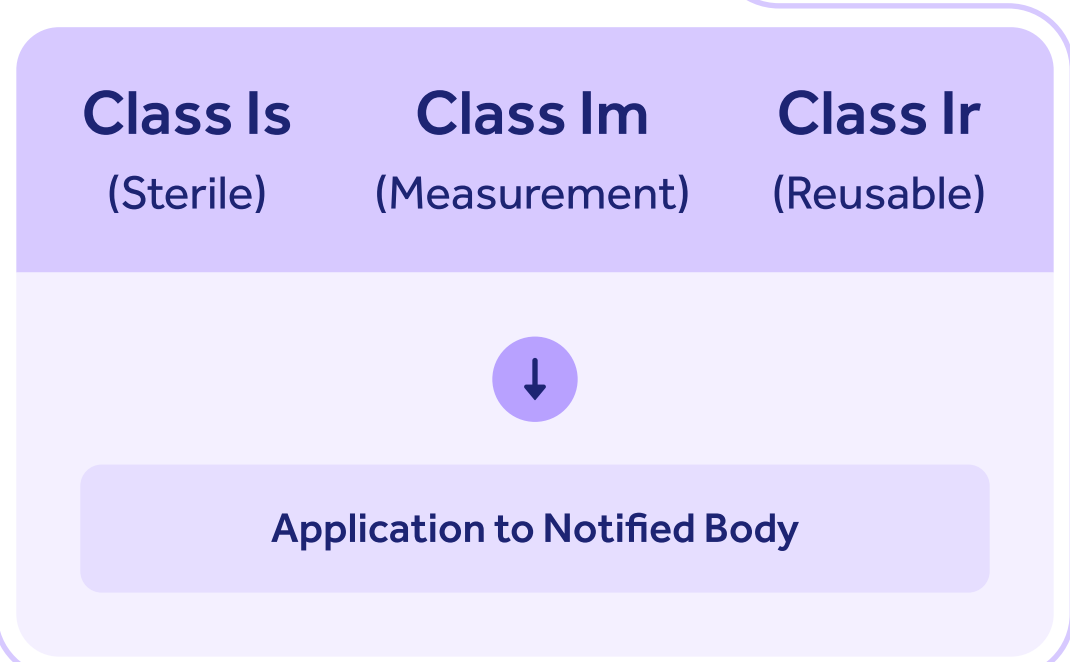
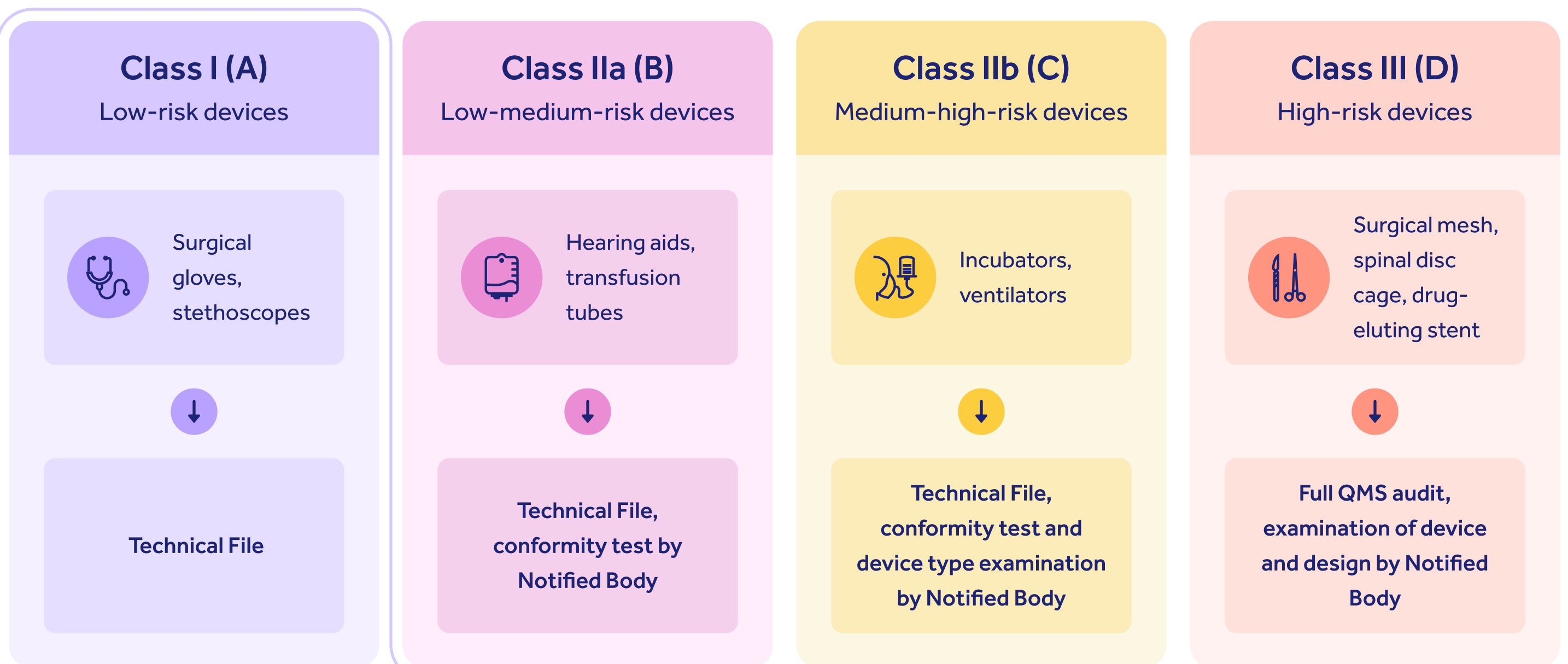
The class and nature of your medical device, and the territory your business plans to operate in, determines the exact regulatory pathway and documentation requirements your company must follow on the route to authorization and market approval. Use this guide to classify your device's class and format, and chart your next steps accordingly.

## What class is my device?

**FDA** Need help classifying? Visit the [FDA's product classification database](#)



**EU** \*Bracketed codes refer to *in vitro* diagnostic medical devices as defined by the IVDR















The MDR's Annex VIII establishes 22 rules and 3 sets of product use durations for classifying a medical device's risk level as follows:

- Non-invasive devices:** Rules 1-4
- Invasive devices:** Rules 5-8
- Active devices:** Rules 9-13
- All other devices:** Rules 14-22

- Transient:** Continuous use, less than an hour
- Short-term:** Continuous use, an hour to 30 days
- Long-term:** 30 days +



# Is my medical device classed as hardware or software as a medical device (SaMD)?

Hardware	Software as medical device (SaMD)	Neither
<p> Any device with no digital component: stethoscopes, syringes, stents, etc.</p>	<p> Independently operating software that serves a medical purpose as a medical device or in vitro diagnostic device: diagnosis, disease management, sample analysis, etc.</p>	<p> Software used for fitness and wellness applications: stress/diet/exercise management, sleep monitoring of a healthy person, etc.</p>
<p> A physical device with core software, firmware or microcode embedded within as an accessory to drive the intended medical purpose: pumps, pacemakers, etc.</p>	<p> Software that interfaces with a hardware device to enhance its functionality without being necessary to it</p>	<p> Software for clinical communication and action management: appointment scheduling, video calls, data encryption, etc.</p>
<p> Any software intrinsically necessary for the operation of a hardware device, even if sold separately, is counted as part of the overall design of the hardware device and is regulated as such.</p>	<p> Software that offers data input parameters for a hardware device, or another SaMD, that serves a medical purpose</p>	<p> Software that monitors the performance of medical and clinical activity: equipment maintenance software, laboratory result analysis software, etc.</p>
	<p> Software serving a medical purpose even if running on general-purpose platforms</p>	<p> <u>Electronic quality management software</u></p>
	<p> Software that analyzes data for medical purposes: MRI scan analysis, imaging data analysis, blood sample analysis, etc.</p>	

## What class is my SaMD?

Significance of information provided by SaMD to healthcare decision			
State of healthcare situation or condition	Treat or diagnose	Drive clinical management	Inform clinical management
Critical	IV	III	II
Serious	III	II	I
Non-serious	II	I	I