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?



Need help classifying? Visit the FDA's product classification database

Class I

Low-risk devices



Surgical instruments, bandages, hospital beds, toothbrushes



General Controls

No approval needed in 74% of cases

Class II

Moderate-risk devices



Syringes, sutures, insulin pumps



General & Special Controls 510(k) approval

Class III

High-risk devices



Ventilators, pacemakers, heart valves



General Controls & Pre-Market Approval (PMA)



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

Class I (A)

Low-risk devices



Surgical gloves, stethoscopes



Technical File

Class IIa (B)

Low-medium-risk devices



Hearing aids, transfusion tubes



Technical File, conformity test by **Notified Body**

Class IIb (C)

Medium-high-risk devices



Incubators, ventilators



Technical File, conformity test and device type examination by Notified Body

Class III (D)

High-risk devices



Surgical mesh, spinal disc cage, drugeluting stent



Full QMS audit, examination of device and design by Notified Body

Class Is

(Sterile)

Class Im

Class Ir

(Measurement)

(Reusable)

Application to Notified Body

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



Any device with no digital component: stethoscopes, syringes, stents, etc.



A physical device with core software, firmware or microcode embedded within as an accessory to drive the intended medical purpose: pumps, pacemakers, etc.



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.

Software as medical device (SaMD)



Independently operating software that serves a medical purpose as a medical device or in vitro diagnostic device: diagnosis, disease management, sample analysis, etc.



Software that interfaces with a hardware device to enhance its functionality without being necessary to it



Software that offers
data input parameters
for a hardware device, or
another SaMD, that
serves a medical
purpose



Software serving a medical purpose even if running on general-purpose platforms



Software that analyzes data for medical purposes: MRI scan analysis, imaging data analysis, blood sample analysis, etc.

Neither



Software used for fitness and wellness applications: stress/ diet/exercise management, sleep monitoring of a healthy person, etc.



Software for clinical communication and action management: appointment scheduling, video calls, data encryption, etc.



Software that monitors
the performance of
medical and clinical
activity: equipment
maintenance software,
laboratory result
analysis software, etc.



Electronic quality
management software

What class is my SaMD?

State of healthcare situation or condition Critical IV III II Serious III I I Non-serious III I I



