

The essential criteria for classification of non-invasive medical devices

Rule 1:

All non-invasive devices to which no other rule applies:
Class I

Rule 2:

Devices intended for channelling blood or for storing blood etc. or for use with devices of class IIa or higher:
Class IIa

Rule 3:

Devices intended for modifying the biological or chemical composition of blood for infusion into the body:
Class IIb

Rule 4:

- Devices which come into contact with injured skin as a mechanical barrier: Class I
- to manage the micro-environment of a wound: Class IIa
- when the dermis has been breached: Class IIb

The essential criteria for classification of invasive medical devices:

Rule 5:

Devices (other than surgically invasive devices) for transient use: Class I
short-term use and use together with active devices of class IIa or higher: Class IIb

Rule 6:

Reusable surgical instruments: Class I
Surgically invasive devices for transient use: Class IIa
Devices intended to supply energy (ionizing radiation): Class IIb
Devices with a biological effect: Class IIb
Devices intended to administer medicines in a manner that is potentially hazardous: Class IIb
Devices which are absorbed: Class IIb
Devices intended for use on the heart or the central circulatory system: Class III

Rule 7:

Surgically invasive devices for short-term use: Class IIa
Devices intended to supply energy (ionizing radiation) and to administer medicines: Class IIb
Devices intended for use on the heart or the central circulatory system: Class III
Devices which come in contact with the central nervous system: Class III
Devices with a biological effect or which are absorbed: Class III

Rule 8:

Devices intended to be placed in teeth: Class IIa
All implantable devices and surgically invasive devices for long-term use to which no other rule applies:
Class IIb
Devices intended for use on the heart or central circulatory system: Class III
Devices to be used in direct contact with the central nervous system: Class III
Devices with a biological effect or which are absorbed: Class III
Devices intended to administer medicines: Class III
Classification of active (power-supplied) devices

Rule 9:

All therapeutic devices intended to administer or exchange energy: Class IIa

All therapeutic devices intended to administer or exchange energy in a potentially hazardous way: Class IIb
All active devices intended to control or monitor the performance of active therapeutic devices: Class IIb

Rule 10:

All active diagnostic devices intended to supply energy: Class IIa
Devices intended to image in vivo distribution of radiopharmaceuticals: Class IIa
All active diagnostic devices intended to supply energy in a potentially hazardous way: Class IIb
All active devices intended to emit ionizing radiation and devices for controlling or monitoring such devices: Class IIb

Rule 11:

All active devices intended to administer and/or remove drugs and body substances to or from the body: Class IIa
All active devices intended to administer and/or remove drugs and body substances to or from the body in a potentially dangerous manner: Class IIb

Rule 12:

All other active devices: Class I

Special rules:

Rule 13:

Devices incorporating a substance which, if used separately, can be considered to be a drug: Class III

Rule 14:

Devices for contraception or the prevention of the transmission of sexually transmitted diseases: Class IIb
Devices for contraception or the prevention of the transmission of sexually transmitted diseases when these are implanted or invasive devices for long-term use: Class III

Rule 15:

Devices intended specifically for disinfecting devices: Class IIa
Devices for disinfecting, cleaning, rinsing and hydrating contact lenses: Class IIb

Rule 16:

Non-active devices for recording X-ray diagnostic images: Class IIa

Rule 17:

Devices manufactured using animal tissues or derivatives: Class III

Rule 18:

Blood bags: Class IIb

