According to MDD
Annex IX [93/42/EEC]

Rule 1
All non-invasive devices are in Class I, unless one of the rules set out hereinafter applies.

Rule 2
All non-invasive devices intended for channelling or storing blood, body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in Class IIa:

- if they may be connected to an active medical device in Class IIa or a higher class,
- if they are intended for use for storing or channelling blood or other body liquids or for storing organs, parts of organs or body tissues, in all other cases they are in Class I.

Rule 3
All non-invasive devices intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion into the body are in Class IIb, unless the treatment consists of filtration, centrifugation or exchanges of gas, heat, in which case they are in Class IIa.

Rule 4
All non-invasive devices which come into contact with injured skin:

- are in Class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates,
- are in Class IIb if they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent,
- are in Class Ila in all other cases, including devices principally intended to manage the micro-environment of a wound.
Rule 5
All invasive devices with respect to body orifices, other than surgically invasive devices and which are not intended for connection to an active medical device:

- are in **Class I** if they are intended for transient use,
- are in **Class IIa** if they are intended for short-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity, in which case they are in **Class I**,
- are in **Class IIb** if they are intended for long-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in Class IIa.

All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to an active medical device in Class IIa or a higher class, are in **Class IIa**.

Rule 6
All surgically invasive devices intended for transient use are in **Class IIa** unless they are

- intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III,
- reusable surgical instruments, in which case they are in Class I,
- intended to supply energy in the form of ionizing radiation in which case they are in Class IIb,
- intended to have a biological effect or to be wholly or mainly absorbed in which case they are in Class IIb,
- intended to administer medicines by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which they are in Class IIb.