

NON-INVASIVE DEVICES

Rule 1

All non-invasive devices are classified as 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, cells or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are classified as class IIa:

– if they may be connected to a class IIa, class IIb or class III active device; or

– if they are intended for use for channelling or storing blood or other body liquids or for storing organs, parts of organs or body cells and tissues, except for blood bags; blood bags are classified as class IIb.

In all other cases such devices are classified as class I.

Rule 3

All non-invasive devices intended for modifying the biological or chemical composition of human tissues or cells, blood, other body liquids or other liquids intended for implantation or administration into the body are classified as class IIb, unless the treatment for which the device is used consists of filtration, centrifugation or exchanges of gas, heat, in which case they are classified as class IIa.

All non-invasive devices consisting of a substance or a mixture of substances intended to be used *in vitro* in direct contact with human cells, tissues or organs taken from the human body or used *in vitro* with human embryos before their implantation or administration into the body are classified as class III.

Rule 4

All non-invasive devices which come into contact with injured skin or mucous membrane are classified as:

– class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates;

– class IIb if they are intended to be used principally for injuries to skin which have breached the dermis or mucous membrane and can only heal by secondary intent;

– class IIa if they are principally intended to manage the micro-environment of injured skin or mucous membrane; and

– class IIa in all other cases.

This rule applies also to the invasive devices that come into contact with injured mucous membrane.