Device Classification.

Extract from Medical Device Directive 93 / 42 / EEC, Annex IX : Classification Criteria.

1. **Definitions for the classification rules.**

1.1 Duration.

Transient

Normally intended for continuous use for less than 60 Minutes.

Short Term

Normally intended for continuous use for not more than 30 Days

Long Term

Normally, intended for continuous use for more than 30 Days

* ***The Temperature Probe is intended for use for periods of less than 30 Days – Hence Short Term.***

1.4 *Active Medical Device*

Any medical device operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change, are not considered to be active.

* ***The Temperature Probe is connected to a monitoring system, therefore active.***

II. IMPLEMENTING RULES.

2. **Implementing rules.**

2.1. Application of the classification rules shall be governed by the intended purpose of the devices.
2.2. If the device is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices. Accessories are classified in their own right separately from the device with which they are used.
2.3. Software, which drives a device or influences the use of a device, falls automatically in the same class.
2.4. If the device is not intended to be used solely or principally in a specific part of the body, it must be considered and classified on the basis of the most critical specified use.
2.5. If several rules apply to the same device, based on the performance specified for the device by the manufacturer, the strictest rules resulting in the higher classification shall apply.

III. CLASSIFICATION.

1. **Non-invasive devices**

1.1 Rule 1.

- All Non-invasive devices are in Class I, unless one of the following rules applies:

- ***The Skin Temperature Probe is intended to allow monitoring of patient temperatures only – Hence Class I.***

2. **Invasive Devices**

2.1 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 to 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 Class IIa.

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

The Rectal / Oesophageal Temperature Probe is a Non-surgically invasive device connected to a Monitor – Hence Class IIa.