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 SpO2 Probe and cables are intended for use for periods of more than 60 Minutes but 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 SpO2 Probe and cables are 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**

3.2 Rule 10.

Active devices intended for diagnosis are in Class IIa:

- if they area intended to supply energy which will be absorbed y the human body, except for devices used to illuminate the patient's body, in the visible spectrum.
- If they are intended to image in vivo distribution of radio pharmaceuticals,
- If they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of CNS in which case they are in Class II(b).

Active devices intended to emit ionising radiation and intended for diagnostic and therapeutic interventional radiology including devices which control or monitor such devices, or which directly influence their performance, are in Class IIb.

* ***The SpO2 Probe and cables are intended to allow monitoring of vital functions, the variation of which could result in danger to the patient – Hence Class II(b)***