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 "TEE" ADAPTER is 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 "TEE" ADAPTER 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**

3.2 Rule 9.

All active therapeutic devices intended to administer or exchange energy are in Class IIa unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they area Class IIb

All active devices intended to control or monitor the performance of therapeutic devices in Class IIb or intended directly to influence the performance of such devices are in Class IIb.

* ***The "TEE" ADAPTER is intended to allow energy to be exchanged between the patient and a monitor – Hence Class IIa.***