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 Apgar Timer is intended for use for periods of not more than 60 Minutes – Hence Transient.***

1.6 *Active Device for Diagnosis*

Any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illness or congenital deformities..

* ***The Apgar Timer is used to Monitor Time-Elapsed, during resuscitation, - Hence an active device.***

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

* ***The Apgar Timer is a Non-invasive device– Hence Class I***