

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 DEVICE is intended for use for periods of not more than XX Minutes – Hence XXXXX*

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 DEVICE is used to Monitor XXXXXXXXXXXX, - Hence an active device.*
- *The DEVICE is used to XXXXXXXXXXXX, - Hence a 0n active device.*