

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 2105 is intended for use as a spot monitor for periods of not more than 60 Minutes
However it can be used for longer periods as it has 48hr trends – Hence Short term.*

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 2105 is used to Monitor SpO2, - Hence an active device.*

1. Non-invasive devices

The 2105 SpO2 is Classified as IIb