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 LIGHT SHIELD is meant for use for periods up to 30 days - hence short term.***

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.

3. **Additional rules applicable to medical devices.**

3.1 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.

* ***The LIGHT SHIELDS act as a barrier between Ultra Violet and Blue Light, and the patient, hence Class IIa .***