

2. Product description

The product covered by this CE technical file is as Chart I

Chart I Product description

Neonatal phototherapy eye protector Product model	Type I Large / Type I Medium / Type I Small / Type I Extra Small
	Type I-N Large / Type I-N Medium / Type I-N Small / Type I-N Extra Small
	Type II Large / Type II Medium / Type II Small / Type II Extra Small
	Type III Large / Type III Medium / Type III Small / Type III Extra Small
	Type IV Large / Type IV Medium / Type IV Small / Type IV Extra Small
	Type V Large / Type V Medium / Type V Small / Type V Extra Small
	Type V-N Large / Type V-N Medium / Type V-N Small / Type V-N Extra Small
	Type VI Large / Type VI Medium / Type VI Small / Type VI Extra Small
	Type VII Large / Type VII Medium / Type VII Small / Type VII Extra Small
Intended use	To protect neonatal baby's eyes by blocking the blue light during phototherapy treatment
Product description	It mainly consists of mask body, shield and adhesive tape. The main raw material is spunlaced non-woven cloth and bonding fabric. It is un-sterilized.
Product classification	The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC
Certification Approach	MDD 93/42/EEC/MDD2007/47/EEC AMEDING ANNEXVII
Standard	EN ISO 14971:2009 Medical Devices - Application of Risk Management to Medical Devices
	EN980:2008 Symbols for use in the labeling of medical devices
	EN ISO 10993-1:2009/AC2010 Biological evaluation of medical devices-Evaluation and testing
	EN ISO 10993-5:2009 Biological evaluation of medical devices-Tests for in vitro cytotoxicity
	ISO 10993-10:2002 AMD 2006 Biological evaluation of medical devices -Tests for irritation and delayed-type hypersensitivity
	EN 1041:2008 Information supplied by the manufacturer of medical devices