

4. Essential Requirements

The neonatal phototherapy eye mask is in accordance with all the essential requirements listed at Annex I, MDD93/42/EEC, MDD2007/47/EEC AMENDING

Annex II Essential requirements

5. Risk Management

We have established and operated quality management system according to EN ISO 14971:2009 Medical Devices - Application of Risk Management to Medical Devices (Risk control program file: Q/ATL-QP7.1-2, version A/0). All the risks related to this product have been reduced to be ACC.

Annex III Risk analysis report