maxtec

SENSING. ANALYSIS. DELIVERY.

DECLARATION OF CONFORMITY

Manufacturer's Name:	Maxtec
Address:	2305 South 1070 West Salt Lake City, Utah 84119 USA
European Representative:	QNET BV Kantstraat 19 NL-5076 NP Haaren The Netherlands
Product:	Neonatal Phototherapy Eye Mask
Model(s):	Eyemax2 (Regular, Preemie, and Micro Sizes)
Classification & GMDN:	I Protection, Equipment, Light Therapy Eyewear 30881
Classification criteria:	Clause 1.1 Rule I of Annex IX of MDD

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documents are retained under the premises of the manufacturer and the European Representative.

Directives:	General application directives: Medical Device Directive, COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 per Annex VII as amended by 2007/47/EC of 5 September 2007
Notified Body:	TÜV SÜD Product Service RIDLERSTRASSE 65, D-80339 MUNICH, Germany Number 0123
EC Certificate No.:	Product is self-certified
Date CE mark was affixed:	20 November 2008

This declaration is considered valid from September 11, 2019 to August 2, 2022.

Signature: Tammy Lavery Date: 09/11/2019

Name: Tammy Lavery

Position: Director of Regulatory and Quality

Applied Standards

The referenced list of harmonized standards for which documented evidence of compliance can be provided includes:

EN ISO 14971:2012
EN 62366:2008
EN 1041:2008
EN ISO 10993:2009
EN ISO 15223-1:2016
EN ISO 13485:2012