maxtec

SENSING. ANALYSIS. DELIVERY.

DECLARATION OF CONFORMITY

Manufacturer's Name:	Maxtec
Address:	6526 South Cottonwood Street Salt Lake City, Utah 84107 USA
European Representative:	QNET BV Hommerterweg 286 6436 AM Amstenrade The Netherlands
Product:	Neonatal Phototherapy Eye Mask
Model(s):	Eyemax2 (Regular, Preemie, and Micro Sizes)
Classification & GMDN:	I Mask, Eye, Phototherapy - 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 II

Notified Body:	TÜV SÜD Product Service -0123 RIDLERSTRASSE 65, D-80339 MUNICH, Germany
EC Certificate No.:	Not Applicable, Product is Self-Certified
Date CE mark was affixed:	20 November 2008

This declaration is considered valid from September 13, 2011 to August 31, 2017.

Signature: Tammy Lavery Date: 8-28-2014

Name: Tammy Lavery
Position: Director of Regulatory & Quality/Maxtec Management Representative

PHONE: 801-266-5300 • TOLL FREE: 800-748-5355 • FAX: 801-270-5590
6526 South Cottonwood St • SLC, Utah • 84107 • USA

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
ISO 15223-1:2012
ISO 13485:2012

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