



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 – R300P01, R300P02 & R300P03 (Regular, Premie, and Micro Sizes)

Classification & GMDN: 2

Is in conformity with the provisions of Council Directive 89/86/EEC Personal Protective Equipment (PPE) and with the national standard transposing harmonized standards.

Is identical to the PPE which is the subject of EC Certification of Conformity as issued by

Notified Body: SGS United Kingdom, Ltd
Weston-super-Mare
BS22 6WA, UK
Notified Body Number: 0120

Is subject to the procedure set out in Article 11A/11B of Directive 89/686/EEC under the supervision of the notified body noted above.

Signature:

Date:

24 Apr 2019

Name: Tammy Lavery
Position: Director of Regulatory and Quality

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PPETF0001

QR-0064 – Rev. 03

RF192 REV H

Applied Standards

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

DIN EN 170:2003 Personal Eye Protection – Ultraviolet filters (Clause 5.2)