



premier o2 solutions

DECLARATION OF CONFORMITY

Manufacturer's Name: Maxtec
Address: 6526 South Cottonwood Street
Salt Lake City, Utah 84107
USA

European Representative: QNET BV
Hommertweg 286
6436 AM Amstenrade
The Netherlands

Product: Neonatal Phototherapy Eye Mask

Model(s): Eyemax2 (Regular, Premie, 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 - CE-0123
RIDLERSTRASSE 65, D-80339 MUNICH, Germany

EC Certificate No.: Not Applicable, Product Self Certified

Date CE mark was affixed: 20 November 2008

This declaration is considered valid from September 13, 2011 to August 31, 2014

Signature:

Date:

September 20, 2011

Name:

Tammy Lavery, RAC

Position:

Director of Regulatory & Quality/Maxtec Management Representative
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