maxtec

premier O2 solutions

DECLARATION OF CONFORMITY

Manufacturer's Name:	**Maxtec, Inc.**
Manufacturer's Address:	**Maxtec, Inc.** **6526 South Cottonwood Street** **Salt Lake City, Utah 84107** **USA**
European Representative:	**QNET BV** **Hommerterweg 286** **6436 AM Amstenrade** **The Netherlands**
Product:	**Neonatal Eye Protector for Phototherapy**
Model(s):	**EyeMax 2 Regular, EyeMax 2 Preemie, and EyeMax 2 Micro**
Classification:	**I**
Classification criteria:	**Clause 1.1 Rule 1 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 concerning medical devices (MDD 93/42/EEC)**

Notified Body:	**TÜV Product Service CE-0123** **RIDLERSTRASSE 65, D-80339 MUNICH, Germany**
EC Certificate No.:	**Not Applicable, Product Self Certified**
Date CE mark was affixed:	**03 September 2004**
Signature:	
Name:	**Debbie Miranda**
Position:	**Director of Quality Assurance/Regulatory Affairs/ISO Representative** **Maxtec, Inc.** **6526 South Cottonwood Street** **Salt Lake City, UT 84107** **General Tel: 801-266-5300** **800-748-5355** **FAX: 801-270-5590**

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