

DECLARATION OF CONFORMITY

Manufacturer's Name: Maxtec, LLC
Address: 2305 South 1070 West
Salt Lake City, Utah 84119
USA

SRN: US-MF-000003961

European Representative: EMERGO EUROPE
Prinsessegracht 20
2515 AP The Hague
The Netherlands

Basic UDI DI: 081777002EyeMax2CU, 0853061006EyeMax22V

Product Name(s): EyeMax2 (Regular, Preemie, and Micro Sizes)

Intended Purpose: The EyeMax2 provides neonatal eye protection during ultraviolet (UV) phototherapy treatment of jaundice.

Risk Class & GMDN: Class I 30881 – Protection, Equipment, Light Therapy Eyewear

Classification Criteria: Clause 4.1 Rule I of Annex VIII EU MDR 2017/745

This EU declaration of conformity is issued under the sole responsibility of the manufacturer. We herewith declare that the above mentioned products meet the provisions of the following EC Council Regulations, Common Specifications and Standards. All supporting documents are retained under the premises of the manufacturer and the European Representative.

Regulations: Medical Device Regulation 2017/745

Notified Body: TÜV SÜD Product Service
RIDLERSTRASSE 65, D-80339 MUNICH, Germany
Number 0123

Conformity Assessment: Annex IX, Conformity Assessment Based on a Quality Management System and on Assessment of Technical Documentation

EC Certificate No.: Product is Self-Certified

Date CE mark was affixed: 20 November 2008

This declaration is considered valid from the date of the signature below.

Signature: _____

Date: _____

May 18, 2021

Name: Sidra Hankins

Position: VP of QA/RA

This Declaration supersedes any preceding Declaration of Conformity for the EyeMax2

Applied Common Specification and Standards

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

EN ISO 13485:2016 (ISO 13485:2016)

EN ISO 14971:2012 (ISO 14971:2007, Corrected version 2007-10-01)

EN 1041:2008

EN ISO 15223-1:2016 (ISO 15223-1:2016, Corrected version 2017-03)

EN ISO 10993-1:2009 (ISO 10993-1:2009)