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 2514 AP The Hague The Netherlands

European Representative SRN: NL-AR-000000116

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 11661 – Eye Pad
Classification Criteria:	Clause 4.1 Rule 1 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:	N/A
Conformity Assessment:	Annex II Product Verification and Validation & Annex III, Technical Documentation on Post-Market Surveillance
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: Sidra M. Hankins Digitally signed by Sidra M. Hankins DN: cn=Sidra M. Hankins, o=Maxtec, LLC, ou=VP of QARA, email=shakins@maxtec.com, c=US Date: 2022.05.26 15:30:29 -04'00' Date: 26 May 2022

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 14971:2019 (ISO 14971:2019)
BS EN ISO 20417:2021
EN ISO 15223-1:2016 (ISO 15223-1:2016, Corrected Version 2017-03)
EN ISO 10993-1:2009 (ISO 10993-1:2009)