UK DECLARATION OF CONFORMITY

Manufacturer:	Maxtec, LLC
Address:	2305 South 1070 West Salt Lake City, Utah 84119 USA
GB Number:	GB085963954000
UK Responsible Person:	Emergo Consulting (UK) Limited c/o Cr 360 – UL International Compass House, Vision Park, Histon Cambridge, CB24 9BZ United Kingdom +44(0) 1223 772 671 UK.Registrations@ul.com
Product Family:	EyeMax2 (Regular, Preemie, and Micro Sizes)
Part numbers/identifiers:	R300P01 R300P02 R300P03
GMDN Code and Term:	11661 – Eye Pad
Basic UDI DI:	081777002 EyeMax2CU 0853061006 EyeMax22V
Intended Use:	The EyeMax2 provides neonatal eye protection during ultraviolet (UV) phototherapy treatment of jaundice.
Device Risk Classification:	Class I in accordance with Annex VIII Rule 1 EU MDR 2017/745
Conformity Assessment Route:	Class I Self-certified (non-sterile, non-measuring devices) Part II of the UK MDR 2002 (as modified by Part II of Schedule 2A to the UK MDR 2002)
Start Date of UKCA mark:	15 March 2023

This declaration of conformity is issued under the sole responsibility of **Maxtec, LLC**. We herewith declare that the above-mentioned products meet the provisions of the following UK Medical device Regulations, Specifications and Standards, and the product has been subjected to relevant conformity assessment procedures. All supporting documents are retained under the premises of the manufacturer.

Applicable Regulations:	Medical Devices Regulations 2002 (SI 2002 No 618, as amended)

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(UK MDR 2002)

Applied Specifications and Standards

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)

Issued by Signature: _____ Date: 14 August, 2023
Name: Sri Divya Kadiyala
Title: Regulatory and Quality Systems Compliance Specialist

Approved by Signature: _____ Date: 14AUG2023

Name: Charly Duffy
Title: Director of Quality Assurance

This Declaration supersedes any preceding Declaration of Conformity for EyeMax2.

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