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
Westervoortsedijk 60,
6827 AT Arnhem
The Netherlands

European Representative SRN: NL-AR-000000116

Basic UDI DI: 081777002EyeMax2CU, 0853061006EyeMax22V

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

Part Number/ Identification	
R300P01	R300P02-006
R300P01-001	R300P02-007
R300P01-002	R300P02-008
R300P01-004	R300P03
R300P01-006	R300P03-001
R300P01-007	R300P03-002
R300P01-008	R300P03-004
R300P01-009	R300P03-006
R300P02	R300P03-007
R300P02-001	R300P03-008
R300P02-002	R300P16
R300P02-004	

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 Technical Documentation & 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: Anvitha AnandRao Digitally signed by Anvitha AnandRao Date: 2025.02.25 09:59:41 -06'00' Date: 25 February 2025

Name: Anvitha Anand Rao
Position: Regulatory and Quality Product Engineering Specialist

Approved by Signature: Rebecca Hudson Digitally signed by Rebecca Hudson DN: cn=Rebecca Hudson, o=PermaPure/Maxtec, ou=VP, RA/QA, email=rhudson@permapure.com, c=US Date: 2025.02.25 12:03:07 -05'00' Date: 25 February 2025
Name: Rebecca Hudson
Position: VP, Regulatory Affairs and Quality Assurance

This Declaration supersedes any preceding Declaration of Conformity for the EyeMax 2.

Applied Common Specifications 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)
EN ISO 20417:2021
EN ISO 15223-1:2021 (ISO 15223-1:2021)
EN ISO 10993-1:2020 (ISO 10993-1:2018)
EN ISO 10993-5:2009 (ISO 10993-5:2009)
EN ISO 10993-10:2023 (ISO 10993-10:2021)
EN ISO 10993-12:2021 (ISO 10993-12:2021)