Declaration of Conformity DC0043 Rev. 01

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Manufacturer Information Name, Address, SRN:	TIDI Products, LLC 570 Enterprise Drive Neenah, WI 54956 USA	SRN: US-MF-000012287
Name of responsible person (PRRC) or designee:	Name: Steve Kahn	Title: VP of Quality and Regulatory
Authorized Representative Contact Information:	Medical Device Safety Service GmbH Schiffgraben 41 30175 Hannover Germany	SRN: DE-AR-000005430
Conformity Assessment Procedure:	1) Medical Device: Annex II & Annex III: Technical documentation including PMS of Regulation (EU) 2017/ 745 of the European Parliament and the Council of the European Union. 2) PPE: EU Type-examination under the requirements of regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II.	
Technical File No.:	TF-0024 Phototherapy Eye Protector	
Product Identification:	Phototherapy Eye Protector	
Product Model Numbers:	See following page(s) for model numbers, GMDNs, descriptions and photo, where appropriate.	
Basic UDI-DI/ Intended purpose:	The intended use of the Phototherapy Eye Protector is used to cover an infant patient's eyes during phototherapy treatment. Basic UDI-DI for Phototherapy Eye Protector: 0190676TF-0024-A3Z	
Device Classification/Rule:	Risk Class I	Rule 1
PPE Category	Category II	
Reference to Common Specifications:	N/A	
EC Certificate:	EC Number: CE 752598	Issue Date: 2022-03-14
Quality Management Certificate:	Number: FM 536366	Effective Date: 05-29-2020
Notified Body Information For QMS:	BSI Group - The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands	

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Notified Body Information for PPE:	BSI Group The Netherlands BV, Say Building, John M Keynesplein 9, 1066 EP, Amsterdam, Netherlands	ID: Notified Body Number: 2797

This declaration of conformity is issued under the sole responsibility of TIDI Products, LLC.
The undersigned hereby declares, on behalf of TIDI Products, LLC, that the products referenced in this declaration comply with the European Medical Devices Regulation, MDR (EU) 2017/745 and with the applicable health and safety requirements of the European Personal Protective Equipment Regulation, PPE (EU) 2016/425 and its relevant transposition into national laws of the member states into which the PPEs are placed. Approval is based on a technical specification supported by specific elements of EN166 to meet the EHSR and Module B and Annex V of the PPE Regulation 2016/425.
We explicitly designate MDSS GmbH to act as our sole Authorized Representative in the European Union for the above indicated products.

Signed for on behalf of TIDI Products LLC, in Neenah, WI.

Name of Authorized Person:	**Title:**	**Date:**
Approval: *Brenda Ammonette*	Manager of Regulatory Compliance	21 September 2022

Model Number (REF)	**Product Name**	**GMDN**	**UDI-DI**
4644	Newborn Eye Protectors, SM Preemie	11661	00190676001927
4645	Newborn Eye Protectors, Preemie	11661	00190676001934
4646	Newborn Eye Protectors, Newborn	11661	00190676001941

Product Name	**Photo (if appropriate)**
Newborn Eye Protectors	

GMDN	**Term**
11661	Eye pad