Declaration of Conformity DC0043 Rev. 0

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: TBD
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: TBD
Conformity Assessment Procedure:	EU Type-examination (module B) set out in Annex V, followed by conformity to type based on internal product control (module C) set out in Annex VI per the Personal Protective Equipment Regulation 2016/425. Class I, Non-Sterile, Non-Measuring Medical Device (as Rule 1 in MDD Annex IX).	
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
Reference to Common Specifications:	N/A	
EC Certificate: *If self-declared add "N/A Self-Declared".*	EC Number: C1827.3TIDI	Issue Date: 16-01-2021
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:	ECS GmbH Huettfeldstrasse 50 73430 AALEN GERMANY	ID: Notified Body Number: 1883

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 medical devices referenced in this declaration comply with the European Medical Devices Regulation, MDR (EU) 2017/745. We explicitly designate MDSS GmbH to act as our sole Authorized Representative in the European Union for the above indicated products.

Approval is based on a technical specification supported by specific elements of EN166 to meet the EHSR and Module B of the PPE Regulation 2016/425.

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

Name of Authorized Person:	**Title:**	**Date:**
Approval: *Brenda Ammonette*	Manager of Regulatory Compliance	25 May 2021

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