EU/UK/AU/CH Declaration of Conformity
DC0043 Rev. 03

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

Manufacturer Information:	TIDI Products, LLC 570 Enterprise Drive Neenah, WI 54956 USA SRN: US-MF-000012287
Person Responsible for Regulatory Compliance (PRRC):	Chris Rahn, Senior Director Quality and Regulatory
European Union (EU) Authorized Representative Contact Information:	MDSS GmbH Schiffgraben 41 30175 Hannover Germany Phone : (+49) 511 6262 8630 SRN: DE-AR-000005430
UK Responsible Person (Medical devices):	Emergo Consulting (UK) Limited c/o Cr360 UL International Compass House, Vision Park Histon Cambridge CB24 9BZ United Kingdom Phone: +44(0) 1223 772 671
United Kingdom (UK) Authorized Rep (PPE) Contact Information:	MDSS-UK RP Ltd. 6 Wilmslow Road, Rusholme Manchester, M14 5TP UNITED KINGDOM Phone: +44 (0)7898 375115
Swiss (CH) Authorized Representative Contact Information:	MDSS CH GmbH Laurenzenvorstadt 61 5000 Aarau Switzerland CHRN: CHRN-AR-20001035.
Product identification:	Phototherapy Eye Protectors
Technical File No.:	TF-0024 Phototherapy Eye Protectors
Product Model Numbers:	See following page(s) for model numbers, GMDNs, descriptions and photo, where appropriate.
EU Legislation and 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.
UK Legislation and Conformity Assessment	UK Medical Devices Regulation 2002 (S1 618) as subsequently amended by the EU Exit Regulations of 2019 (SI 791) and 2020 (SI 1478).

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Procedure:	Conformity to Part II of the UK MDR 2002, Annex VII (as modified by Part II of Schedule 2A to the UK MDR 2002). Conforms to essential requirements according to Annex II of the PPE Regulation 2016/425 as brought into UK law and amended and limited clauses of EN 16:2001. UKCA Type examination certificate UKCA 760423 under the requirements of The Product Safety and Metrology etc. (Amendment etc.)(EU Exit) Regulations 2020 (SI 2020/676) relating to PPE 2016/745 Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II.	
Australia (AU) Legislation and Conformity Assessment Procedure:	Not marking in AU.	
CH Legislation and Conformity Assessment Procedure:	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. 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.	
Intended purpose:	The intended use of the Phototherapy Eye Protector is used to cover an infant patient's eyes during phototherapy treatment.	
EMDN Code:	M040301 – Eyepads, cotton or non-woven material	
Basic UDI-DI:	Basic UDI-DI for Phototherapy Eye Protector: 0190676TF-0024-A3Z	
Device Classification in EU/CH:	Risk Class I, Rule 1	
PPE Category in EU/CH:	Category II	
PPE Category in UK:	Category II	
Device Classification/ Rule in Australia (AU):	NA – not marketing in AU	
Australian Client ID No.	TIDI's AU Client ID No.: 49283	
Reference to Common Specifications:	N/A	
EC Certificate:	EC Number: CE 752598	Issue Date: 2022-03-14
UKCA Certificate:	Number: UKCA 760423	Issue Date: 14 March 2022
Quality Management Certificate - ISO 13485	Number: FM 536366	Effective Date: 29 May 2023
MDSAP Certificate	Number: MDSAP 703786	Effective Date: 29 May 2023

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Notified Body for QMS:	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam, The Netherlands Notified Body Number: 2797
Notified Body for EU Conformity Assessment:	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam, The Netherlands Notified Body Number: 2797
Approved Body for UK Conformity Assessment (PPE)*:*	BSI UK Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, United Kingdom MK5 8PP Approved Body Number 0086

For European Union (Device & PPE products)
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.

For United Kingdom (Device & PPE) products):
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/PPE referenced in this declaration comply with the UK Medical Devices Regulation 2002 (93/42/EEC) and the Personal Protection Equipment Regulation 2016/425 as brought into UK law and amended. We explicitly designate Emergo Consulting (UK) Limited to act as our sole Responsible Person in the UK for the above indicated medical devices and we explicitly designate MDSS-UK RP Ltd. to act as our sole Authorized Representative in the UK for the above indicated PPE products.

For Switzerland (Device & PPE products):
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 54956

Name of TIDI Representative:	**Title, Function**	**Date**

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Brenda Ammonette		
Approval: *Brenda Ammonette*	**Approval:** Regulatory Compliance Manager	 July 12. 2023

Product Name, Model Number, GMDN, and UDI-DI to which this declaration applies			
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	

Glossary of Global Medical Device Nomenclature (GMDN) Terms	
GMDN	**Term**
11661	Eye pad