UK Declaration of Conformity
DC0048 Rev. 02

In accordance with UK Government guidance

Manufacturer Contact:	TIDI Products LLC 570 Enterprise Drive Neenah, WI 54956 USA	Management Representative: Brenda Ammonette, Regulatory Compliance Manager
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
UK Authorized Representative (PPE)	MDSS-UK RP Ltd. 6 Wilmslow Road, Rusholme Manchester, M14 5TP United Kingdom	Phone: +44 (0)7898 375115
UK Legislation and Conformity Assessment Route:	UK Medical Devices Regulation 2002 (S1 618) as subsequently amended by the EU Exit Regulations of 2019 (SI 791) and 2020 (SI 1478). 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.	
Technical File No.:	TF-0024 Phototherapy Eye Protector	
Product Scope:	Phototherapy Eye Protectors	
Model Numbers:	See following page(s) for model numbers, GMDNs, descriptions and photos, where appropriate	
Device Classification:	Risk Class I	Rule 1
PPE Classification:	Category II	
EC Certificate: *If self-declared add "N/A Self-Declared".*	EC Number: N/A Self-Declared	Issue Date: N/A Self-Declared
UKCA Certificate (PPE):	Number: UKCA 760423	Issue Date: 14 March 2022

UK Declaration of Conformity
DC0048 Rev. 02

In accordance with UK Government guidance

Quality Management Certificate:	Number: FM 536366	Issue Date: 29 May 2020
EU Notified Body (QMS)	BSI Group The Netherlands B.V.	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands
UK Approved Body (PPE):	BSI Assurance UK Ltd.	BSI Assurance UK Ltd – AB 0086 Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP

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.

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

Name of Authorized Person	Title	Date
Brenda Ammonette	**Regulatory Compliance Manager**	**25 Aug 2022**

UK Declaration of Conformity
DC0048 Rev. 02

In accordance with UK Government guidance

Product Model Numbers, Description, and GMDN code to which this declaration applies		
Model Number (REF)	**Product name**	**GMDN**
4644	Newborn Eye Protectors, SM Preemie	11661
4645	Newborn Eye Protectors, Preemie	11661
4646	Newborn Eye Protectors, Newborn	11661

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

GMDN	**Term**
11661	Eye pad

The products to which this declaration relates are developed and manufactured in conformity with the following standard(s).	
UK Standard	**Title**
ISO 13485	Quality Management System
ISO 14971	Standard for Medical Devices - Application of Risk Management