



## EU/UK/AU/CH Declaration of Conformity DC0043 Rev. 05

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

<b>Manufacturer Information:</b>	TIDI Products, LLC 570 Enterprise Drive Neenah, WI 54956 USA SRN: US-MF-000012287
<b>Person Responsible for Regulatory Compliance (PRRC):</b>	Chris Rahn, VP Quality & Regulatory
<b>European Union (EU) Authorized Representative Contact Information:</b>	MDSS GmbH Schiffgraben 41 30175 Hannover Germany Phone: (+49) 511 6262 8630 SRN: DE-AR-000005430
<b>UK Responsible Person (Medical devices):</b>	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
<b>United Kingdom (UK) Authorized Rep (PPE) Contact Information:</b>	MDSS-UK RP Ltd. Parkway House, Palatine Rd, Northenden, Wythenshawe, Manchester M22 4DB United Kingdom
<b>Swiss (CH) Authorized Representative Contact Information:</b>	MDSS CH GmbH Laurenzenvorstadt 61 5000 Aarau Switzerland CHRN: CHRN-AR-20001035.
<b>Product identification:</b>	Phototherapy Eye Protector
<b>Technical File No.:</b>	TF-0024 Phototherapy Eye Protector
<b>Product Model Numbers:</b>	See following page(s) for model numbers, GMDNs, descriptions and photo, where appropriate.
<b>EU Legislation and Conformity Assessment Procedure:</b>	<ol style="list-style-type: none"> <li>1) Medical Device: Annex II &amp; Annex III: Technical documentation including PMS of Regulation (EU) 2017/ 745 of the European Parliament and the Council of the European Union.</li> <li>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.</li> </ol>



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<b>UK Legislation and Conformity Assessment Procedure:</b>	<p>UK Medical Devices Regulation 2002 (SI 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).</p> <p>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.</p>	
<b>Australia (AU) Legislation and Conformity Assessment Procedure:</b>	<p>Not marking in AU.</p>	
<b>CH Legislation and Conformity Assessment Procedure:</b>	<p>Medical Device: Annex II &amp; Annex III: Technical documentation including PMS of Regulation (EU) 2017/ 745 of the European Parliament and the Council of the European Union.</p> <p>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.</p>	
<b>Intended purpose:</b>	<p>The intended use of the Phototherapy Eye Protector is used to cover an infant patient's eyes during phototherapy treatment.</p>	
<b>EMDN Code:</b>	<p>M040301 – Eyepads, cotton or non-woven material</p>	
<b>Basic UDI-DI:</b>	<p>Basic UDI-DI for Phototherapy Eye Protector: 0190676TF-0024-A3Z</p>	
<b>Device Classification in EU/CH:</b>	<p>Risk Class I, Rule 1</p>	
<b>PPE Category in EU/CH:</b>	<p>Category II</p>	
<b>PPE Category in UK:</b>	<p>Category II</p>	
<b>Device Classification/ Rule in Australia (AU):</b>	<p>NA – not marketing in AU</p>	
<b>Australian Client ID No.</b>	<p>TIDI's AU Client ID No.: 49283</p>	
<b>Reference to Common Specifications:</b>	<p>N/A</p>	
<b>EC Certificate:</b>	<p>EC Number: CE 752598</p>	<p>Issue Date: 2022-03-14</p>



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<b>UKCA Certificate:</b>	Number: UKCA 760423	Issue Date: 14 March 2022
<b>Quality Management Certificate - ISO 13485</b>	Number: FM 536366	Effective Date: 29 May 2023
<b>MDSAP Certificate</b>	Number: MDSAP 703786	Effective Date: 29 May 2023
<b>Notified Body for QMS:</b>	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam, The Netherlands Notified Body Number: 2797	
<b>Notified Body for EU Conformity Assessment:</b>	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam, The Netherlands Notified Body Number: 2797	
<b>Approved Body for UK Conformity Assessment (PPE):</b>	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



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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**

<b>Name of TIDI Representative:</b> Sara Carney	<b>Title, Function</b>	<b>Date</b>
<b>Approval:</b> Signed by Sara Carney	<b>Sr. Regulatory Affairs Compliance Manager</b>	2/10/2026
Sara Carney	I approve this document 2/10/2026   2:36:49 PM PST	

**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 Premie	11661	00190676001927
4645	Newborn Eye Protectors, Premie	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