



EU/UK/AU/CH Declaration of Conformity DC0003 Rev. 18

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
United Kingdom (UK) Authorized Rep 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:	NA – not applicable
Product identification:	Eyewear and Face Shields
Technical File No.:	TF-0021: TIDI Products Eyewear and Face Shields
Product Model Numbers:	See following page(s) for model numbers, and descriptions.
EU Legislation and 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
UK Legislation and Conformity Assessment Procedure:	Eyewear: 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 of Regulation 2016/425 on personal protective equipment as brought into UK law and amended.
Australia (AU) Legislation and Conformity Assessment Procedure:	Clause(s) 6.6 of Schedule 3 Part 6 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002.
CH Legislation and 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
Intended purpose:	Eyewear: The eyewear is intended to provide eye protection from splashing, spraying, or splattering of liquids. Grab 'n Go Face Shield: The face shield is intended to provide eye and face protection from splashing, spraying, or splattering of liquids.



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	Assemble 'n Go Face Shield: The face shield is intended for basic eye protector use.	
EMDN Code:	N/A	
Basic UDI-DI:	N/A	
PPE Category in EU/CH:	Category II	
PPE Category in UK:	Category II	
Device Classification/ Rule in Australia (AU):	Class 1	Rule 2.1
Australian Client ID No.	TIDI's AU Client ID No.: 49283	
Reference to Common Specifications:	N/A	
EC Certificate:	Number: CE 683721	Issue Date: 07 December 2018
UKCA Certificate:	Number: 750689	Issue Date: August 08, 2021
Quality Management Certificate - ISO 13485	Number: FM 536366	Effective Date: 29 May 2023
MDSAP Certificate	Number: MDSAP 703786	Effective Date: 29 May 2023
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:	BSI UK Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, United Kingdom MK5 8PP Approved Body Number 0086	
For European Union (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 personal protective equipment complies with the European Personal Protective Equipment Regulation 2016/425, and its relevant transposition into national laws		



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of the member states into which the PPEs are placed. 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.

For United Kingdom (Eyewear (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 personal protective equipment complies with Regulation 2016/425 on personal protective equipment as brought into UK law and amended. We explicitly designate MDSS-UK RP Ltd. to act as our sole Authorized Representative in the UK 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 as brought into UK and amended.

For Australia (Non-Sterile devices):

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 each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles, and the classification rules before being supplied under clause(s) 6.6 of Schedule 3 Part 6 to the Australian Therapeutic Goods Administration Medical Device Regulation 2002.

Signed for on behalf of TIDI Products LLC, in Neenah, WI 54956

Name of TIDI Representative: Brenda Ammonette	Title, Function	Date
Approval: <i>Brenda Ammonette</i>	Approval: Regulatory Compliance Manager	July 12, 2023



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Product Name and Model Number to which this declaration applies (Skus in this table are marketed in EU & AU)	
Model Number	Product Name
9210A-100	TIDI Shield Grab 'n Go Eye Shields
9210A-100AN	TIDI Shield Grab 'n Go Eye Shields
9210-250DSP	TIDI Shield Assemble 'n Go Replacement Lenses
9211-400	TIDI Shield Assemble 'n Go Replacement Frames
9211-400AN	TIDI Shield Assemble 'n Go Replacement Frames
9210-100	TIDI Shield Assemble 'n Go Replacement Lenses
9210-100US	TIDI Shield Assemble 'n Go Replacement Lenses
9210-250	TIDI Shield Assemble 'n Go Replacement Lenses
9210-250DSPAN	TIDI Shield Assemble 'n Go Replacement Lenses
9211-100	TIDI Shield Assemble 'n Go Replacement Frames
9210A-50	TIDI Shield Grab 'n Go Pre-Assembled Eye Shields Assorted Colored Frames with Clear Lenses
9300FE-50	TIDI Shield Flip 'n Go Eye Shields
9210-GRAING	TIDI Shield Assemble 'n Go Replacement Lenses
9210-HERATY	Eye Shield Disposable Clear Lenses
9210A-50-HERATY	TIDI Shield Grab 'n Go Pre-Assembled Eye Shields
SV250L	Halyard Safeview Eyewear Replacement Lenses
SV100F	Halyard Safeview Eyewear Frames
SV50A	Halyard Safeview Eyewear Assembled Glasses
FS96FC	TIDI Shield Grab 'n Go FaceShield
2211-100	TIDI Shield Face Protection Visors and Nose Pieces



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Product Name and Model Number to which this declaration applies (Skus in this table are marketed in EU & AU)	
Model Number	Product Name
2210-100	TIDI Shield Assemble 'n Go FaceShield Replacement Lenses
TIDIFS96	TIDI Shield Grab 'n Go FaceShield
TIDIFS96-10PK	TIDI Shield Grab 'n Go FaceShield

Product Model Number and Description to which this declaration applies. (Below skus are marketed in UK only)	
Model Numbers	Description
9210-100	TIDIShield Assemble 'n Go Eyewear Replacement Lenses
9211-100	TIDIShield Assemble 'n Go Eyewear Replacement Frames
2210-100	TIDIShield Assemble 'n Go FaceShield Replacement Lenses
2211-100	TIDIShield Face Protection Visors and Nose Pieces
SV250L	Halyard Safeview Eyewear Replacement Lenses
SV100F	Halyard Safeview Eyewear Frames
SV50A	Halyard Safeview Eyewear Assembled Glasses

Glossary of Global Medical Device Nomenclature (GMDN) Terms (for AU only)	
GMDN	Term
58376	Eye splash shield, single use

The products to which this declaration relates are developed and manufactured in conformity with the following standard(s).	
Safety Standard	Title
EN ISO 13485	Quality Management System
EN 166	Personal eye protection. Specifications (Partial)
EN 167	Personal eye protection. Optical test methods. (Partial)
EN 168	Personal eye-protection. Non-optical test methods. (Partial)