



Declaration of Conformity DC0025 Rev. 06

This is a declaration of conformity made under clause(s) 6.6 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002, Australia.

Manufacturer and Contact:	TIDI Products, LLC 570 Enterprise Drive Neenah, WI 54956	Management Representative: Amanda Altan Regulatory Affairs Manager
Technical File No.:	TF-0021: TIDI Products Eyewear and Face Shields	
Product Scope:	Eyewear	
Model Numbers:	See following page(s) for model numbers, GMDNs, and descriptions.	
Device Classification:	Class 1	Rule 2.1
EC Certificate:	CE 683721	
Conformity Route	Number: CE 683721	Issue Date: 07 December 2018
MDSAP Certificate	Number: MDSAP 703786	Issue Date: 29 May 2020
Quality Management Certificate - ISO 13485:	Number: FM 536366	Issue Date: 03 Aug 2018
Notified Body:	BSI Group The Netherlands B.V.	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands Telephone: +31 20 346 0780 Notified Body Number: 2797
Standards Applied:	See following pages for list of standards applied.	
<p>This declaration of conformity is issued under the sole responsibility of TIDI Products, LLC. The devices referenced in this declaration are provided non-sterile.</p> <p>The undersigned hereby declares, on behalf of TIDI Products, LLC, that the medical devices referenced in this declaration to which the system has been applied, complies with the applicable provisions of the essential principles, the classification rules, and the quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.</p>		
Signed for on behalf of TIDI Products LLC, by Regulatory Affairs Manager; Amanda Altan, in Neenah Wisconsin.		
Signature:		Date: 10 January 2022



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Product Model Number and Description to which this declaration applies.	
Model Numbers	Description
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
9210A-100US	TIDIShield Grab 'n Go Eye Shields
9210-GRAING	TIDIShield 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
FS96EC	TIDI Shield Grab 'n Go Faceshield
FS96FC	TIDI Shield Grab 'n Go Faceshield
2211-100	TIDI Shield Face Protection Visors and Nose Pieces
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

Glossary of Global Medical Device Nomenclature (GMDN) Terms

GMDN	Term
58376	Eye splash shield, single use



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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)