

EU Declaration of Conformity DC0003 Rev. 15

	T		
Manufacturer and Contact:	TIDI Products LLC 570 Enterprise Drive Neenah, WI 54956 USA	Management Representative: Amanda Altan Manager, Regulatory Affairs	
Authorized Representative	Medical Device Safety Service GmbH Schiffgaben 41 30175 Hannover Germany	Telephone: 49 511 6262 8630 Fax: 49 511 6262 8633	
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		
Technical File No.:	TF-0021: Eyewear and Face Shields PPE		
Product Scope:	Eyewear and Face Shields		
Model Numbers:	See following page(s) for model numbers and descriptions.		
PPE Category:	Category II		
EC Type-Certificate:	Number: CE 683721	Issue Date: 07 December 2018	
Quality Management Certificate:	Number: FM 536366	Effective Date: 29 May 2020	
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	
This declaration of conformity is issued under the sole responsibility of TIDI Products, LLC. The undersigned			

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 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.

Signed for on behalf of TIDI Products LLC, by the Manager of Regulatory Affairs; Amanda Altan, in Neenah, Wisconsin.

Name of Authorized Person	Title	Date
Amanda Alfan Approval:	Regulatory Affairs Manager	August 4 2021



EU Declaration of Conformity DC0003 Rev. 15

Product Model Number and Description to which this declaration			
applies.			
Model Numbers	Description		
9210A-100	TIDIShield Grab 'n Go Eye Shields		
9210A-100AN	TIDIShield Grab 'n Go Eye Shields		
9210-250DSP	TIDIShield Assemble 'n Go Replacement Lenses		
9211-400	TIDIShield Assemble 'n Go Replacement Frames		
9211-400AN	TIDIShield Assemble 'n Go Replacement Frames		
9210-100	TIDIShield Assemble 'n Go Replacement Lenses		
9210-100US	TIDIShield Assemble 'n Go Replacement Lenses		
9210-250	TIDIShield Assemble 'n Go Replacement Lenses		
9210-250DSPAN	TIDIShield Assemble 'n Go Replacement Lenses		
9211-100	TIDIShield Assemble 'n Go Replacement Frames		
9210A-50	TIDIShield Grab 'n Go Pre-Assembled Eye Shields Assorted Colored Frames with Clear Lenses		
9211-GRAING	Resposables EyeShield		
9300FE-50	TIDIShield 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	TIDIShield Grab 'n Go Pre-Assembled Eye Shields		
9210-TOLCO	Resposable EyeShield Disposable Lenses		
9211P-100-MUR	TIDI Resposable EyeShield Frames		
SV250L	Halyard Safeview Eyewear Replacement Lenses		
SV100F	Halyard Safeview Eyewear Frames		
SV50A	Halyard Safeview Eyewear Assembled Glasses		
FS96EC	TIDIShield Grab 'n Go FaceShield		
FS96FC	TIDIShield Grab 'n Go FaceShield		
2211-100	TIDIShield Face Protection Visors and Nose Pieces		
2210-100	TIDIShield Assemble 'n Go Faceshield Replacement Lenses		
TIDIFS96	TIDIShield Grab 'n Go Faceshield		
TIDIFS96-10PK	TIDIShield Grab 'n Go Faceshield		

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		
BS EN 166	Personal eye protection. Specifications (Partial)		
BS EN 167	Personal eye protection. Optical test methods. (Partial)		
BS EN 168	Personal eye-protection. Non-optical test methods. (Partial)		