




## EU Declaration of Conformity DC0003 Rev. 3

<b>Manufacturer:</b>	TIDI Products LLC 570 Enterprise Drive Neenah, WI 54956 USA	Management Representative: Amanda Altan Manager, Regulatory Affairs	
<b>Authorized Representative</b>	Medical Device Safety Service GmbH Schiffgaben 41 30175 Hannover Germany	Telephone: 49 511 6262 8630 Fax: 49 511 6262 8633	
<b>Conformity Assessment Procedure:</b>	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		
<b>Technical File No.:</b>	TF-0021 TIDI Products Eyewear		
<b>Product:</b>	Eyewear		
<b>Model Numbers:</b>	See following page(s) for model numbers and descriptions.		
<b>Device Category:</b>	Category II		
<b>EU Type Examination Certificate:</b>	Number: CE 683721	Issue Date: 07 December 2018	Expiry Date: 07 December 2023
<b>Quality Management Certificate:</b>	Number: FM 536366	Issue Date: 25 August 2017	Expiry Date: 24 August 2020
<b>Notified Body:</b>	BSI Assurance UK Limited NB0086	Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP Telephone: +44 845 080 9000	

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 devices are placed. We explicitly designate Medical Device Safety Service 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
<b>Approval:</b>  Amanda Altan	Manager of Regulatory Affairs	22 Jan 2020





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Product Model Number and Description to which this declaration applies.	
Model Numbers	Description
9210A-100	TIDIShield Grab 'n Go Eye Shields
9210-250DSP	TIDIShield Assemble 'n Go Replacement Lenses
9211-400	TIDIShield Assemble 'n Go Replacement Frames
9210-100	TIDIShield Assemble 'n Go Replacement Lenses
9210-25	Reposable Eyeshield Disposable Lenses
9210-250	TIDIShield Assemble 'n Go Replacement Lenses
9210-50	TIDIShield Assemble 'n Go Replacement Eye Shields
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
9452-10	TIDIShield Assemble 'n Go Lenses and Frames
9210A-100HHW	TIDIShield Grab 'n Go Disposable Eye Shields
9209	TIDIShield Disposable Eye Shield Frames & Lenses
9210-100-6	TIDIShield Assemble 'n Go Replacement Lenses
9452	TIDIShield Assemble 'n Go Office Pack
9452-MUR	TIDI EyeShield Office Pack
9210-GRAING	TIDIShield Assemble 'n Go Replacement Lenses
9210-250-MUR	TIDIShield Assemble 'n Go Replacement Lenses
9210COREMEC	EYEShield Lenses Disposable Clear
9210-HERATY	EYE Shield Disposable Clear Lenses
9210A-50-HERATY	TIDIShield Grab 'n Go Pre-Assembled Eye Shields
9210-IMA	EYEShield Disposable Clear EyeShields
9210A-50-IMA	TIDIShield Grab 'n Go Pre-Assembled Eye Shields
9210-MEDINTL	EYEShield Disposable Clear Lens
9210-PACBIO	EYEShield Disposable Clear EyeShields
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





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

These devices are labeled in the following languages: English, Spanish, French, German, Dutch, Italian, Portuguese, Polish, Hungarian, Slovak, Swedish, Norwegian, Danish, Finnish, and Czech.