




# EU Declaration of Conformity DC0004 Rev. 1

<b>Manufacturer:</b>	TIDI Products LLC 570 Enterprise Drive Neenah, WI 54956 USA	Management Representative: Joy Greidanus Director, 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 Face Shields		
<b>Product:</b>	Face Shield		
<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 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 Director of Regulatory Affairs; Joy Greidanus, in Neenah, Wisconsin.

Name of Authorized Person	Title	Date
Approval:  Joy Greidanus	Director of Regulatory Affairs	11 DEC 2018





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Product Model Number and Description to which this declaration applies.	
Model Numbers	Description
2210-100	TIDIShield Assemble 'n Go Faceshield Replacement Lenses
2210-40	TIDIShield Assemble 'n Go Replacement Face Shields
2211-100	TIDIShield Face Protection Visors and Nose Pieces
2211-50	TIDIShield Reusable Visor
2211-80DSP	TIDIShield Visors for Assemble 'n Go Faceshields
FS96EC	TIDIShield Grab 'n Go Faceshields
FS96FC	TIDIShield Grab 'n Go Faceshields
FS40EC	TIDIShield Grab 'n Go Disposable Face Shields Enhanced Coverage
FS40FC	TIDIShield Grab 'n Go Disposable Face Shields Full Coverage
2210-40-6	TIDIShield Assemble 'n Go Faceshield Replacement Lenses
2452-6	TIDIShield Assemble 'n Go Face Shield Combo Pack
2452-MUR	TIDI Resposable FaceShield Office Pack
2452	TIDI Products Resposable FaceShield
2209	TIDIShield Assemble 'n Go Faceshields

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.

