



# EU/UK/AU/CH Declaration of Conformity DC0039 Rev. 13

**This Declaration of Conformity is issued under the sole responsibility of the manufacturer.**

<b>Manufacturer Information:</b>	TIDI Products, LLC 570 Enterprise Drive Neenah, WI 54956 USA SRN: US-MF-000012287
<b>Person Responsible for Regulatory Compliance (PRRC):</b>	Chris Rahn, Senior Director Quality & Regulatory
<b>European Union (EU) Authorized Representative Contact Information:</b>	MDSS GmbH Schiffgraben 41 30175 Hannover Germany Phone: (+49) 511 6262 8630 SRN: DE-AR-000005430
<b>United Kingdom (UK) Responsible Person Contact Information:</b>	Emergo Consulting (UK) Limited c/o Cr360 UL International Compass House, Vision Park Histon Cambridge CB24 9BZ, United Kingdom Phone: +44(0) 1223 772 671
<b>Swiss (CH) Authorized Representative Contact Information:</b>	MDSS CH GmbH Laurenzenvorstadt 61 5000 Aarau Switzerland CHRN: CHRN-AR-20001035.
<b>Product identification:</b>	Instrument Sheaths and Camera Covers (Dental barriers)
<b>Technical File No.:</b>	TF-0019: TIDI Products Dental Barrier Family
<b>Product Model Numbers:</b>	See following page(s) for model numbers, GMDNs, descriptions and photo, where appropriate
<b>EU Legislation and Conformity Assessment Procedure:</b>	Annex II & Annex III: Technical documentation including PMS of Medical Device Regulation (EU) 2017/ 745 of the European Parliament and the Council of the European Union.
<b>UK Legislation and Conformity Assessment Procedure:</b>	UK Medical Devices Regulation 2002 (SI 618) as subsequently amended by the EU Exit Regulations of 2019 (SI 791) and 2020 (SI 1478).  Conformity to Part II of the UK MDR 2002, Annex VII (as modified by Part II of Schedule 2A to the UK MDR 2002).
<b>Australia (AU) Legislation and Conformity Assessment Procedure:</b>	Clause(s) 6.6 of Schedule 3 Part 6 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002
<b>CH Legislation and Conformity Assessment Procedure:</b>	Annex II & Annex III: Technical documentation including PMS of Medical Device Regulation (EU) 2017/ 745 of the European Parliament and the Council of the European Union.



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<b>Intended purpose:</b>	Dental Barriers are used as an accessory to hand-held dental equipment. The dental barriers are intended to serve as a disposable barrier for dental instruments to protect the dental instrument from contamination.	
<b>EMDN Code:</b>	EMDN (European Medical Device Nomenclature) code for Dental Barriers: <ul style="list-style-type: none"> <li>• T030202 Camera covers</li> <li>• T030102 Cover sheaths, Instrument, and equipment</li> </ul>	
<b>Basic UDI-DI:</b>	Basic UDI-DI for dental barriers: Curing Light sleeves    0618125TF-0019-AXS Camera Covers            0618125TF-0019-BXU X-ray sensor sheaths    0618125TF-0019-CXW General                     0618125TF-0019-DXY	
<b>Device Classification/ Rule in EU/CH:</b>	Risk Class I	Rule 5
<b>Device Classification/ Rule in UK:</b>	Risk Class I	Rule 5
<b>Device Classification/ Rule in Australia (AU):</b>	Class 1	Rule 3.1
<b>Australian Client ID No.</b>	TIDI's AU Client ID No.: 49283	
<b>Reference to Common Specifications:</b>	NA	
<b>EC Certificate:</b>	EC Number: N/A Self-Declared	Issue Date: N/A Self-Declared
<b>UKCA Certificate:</b>	EC Number: N/A Self-Declared	Issue Date: N/A Self-Declared
<b>Quality Management Certificate - ISO 13485</b>	Number: FM 536366	Effective Date: 29 May 2023
<b>MDSAP Certificate</b>	Number: MDSAP 703786	Effective Date: 29 May 2023
<b>Notified Body for QMS:</b>	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam, The Netherlands NB No. 2797	
<b>Notified Body for EU Conformity Assessment: (if applicable)</b>	NA	
<b>Approved Body for UK Conformity Assessment: (if applicable)</b>	NA	



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## For European Union (Non-sterile 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 medical devices referenced in this declaration comply with the European Medical Devices Regulation; MDR (EU) 2017/745. We explicitly designate MDSS GmbH to act as our sole Authorized Representative in the European Union for the above indicated products.

## For United Kingdom:

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 medical devices referenced in this declaration comply with the UK Medical Devices Regulation 2002 (SI 618) as subsequently amended by the EU Exit Regulations of 2019 (SI 791) and 2020 (SI 1478). We explicitly designate Emergo Consulting (UK) Limited to act as our sole Responsible Person in the UK for the above indicated products.


## For Australia (Non-sterile 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 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.

## For Switzerland:

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 medical devices referenced in this declaration comply with the applicable parts of the MedDO. These are class I medical devices that declare conformity to Regulation (EU) 2017/745 (MDR). We explicitly designate MDSS CH GmbH to act as our sole Authorized Representative in Switzerland for the above indicated products.

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

<b>Name of TIDI Representative:</b> Javorka Spalevic	<b>Title, Function</b>	<b>Date</b>
<b>Approval:</b> 	<b>Approval:</b> Sr. Regulatory Affairs Specialist	07/10/2023



## EU/UK/AU/CH Declaration of Conformity DC0039 Rev. 13

Product Name, Model Number, GMDN, and UDI-DI to which this declaration applies			
Model Number (REF)	Product Name	GMDN	UDI-DI
6554489 (CS1500)	TIDIShield Camera Covers with The SureClear Window	12535	00618125141487
X00128	TIDIShield X-Ray Sensor Sheaths	12535	00618125184002
X00129	TIDIShield X-Ray Sensor Sheaths	12535	00618125184019
20710	TIDIShield Camera Covers with The SureClear Window	12535	00618125115389
20800	TIDIShield Camera Covers with The SureClear Window	12535	00618125115389
20808	TIDIShield Camera Covers with The SureClear Window	12535	00618125133055
20812	TIDIShield Camera Covers with The SureClear Window	12535	00618125102228
20816	TIDIShield Camera Covers with The SureClear Window	12535	00618125102259
20818	TIDIShield Camera Covers with The SureClear Window	12535	00618125102266
20819	TIDIShield X-Ray Sensor Sheaths	12535	00618125102273
20824	TIDIShield X-Ray Sensor Sheaths	12535	00618125102310
20825	TIDIShield X-Ray Sensor Sheaths	12535	00618125102327
20831	TIDIShield Camera Covers with The SureClear Window	12535	00618125102341
20834	TIDIShield Camera Covers with The SureClear Window	12535	00618125102365
20840	TIDIShield Camera Covers with The SureClear Window	12535	00618125102402
20841	TIDIShield X-Ray Sensor Sheaths	12535	00618125102419
20855	TIDIShield Camera Covers with The SureClear Window	12535	00618125102495
20856	TIDIShield Camera Covers with The SureClear Window	12535	00618125102501
20861	TIDIShield X-Ray Sensor Sheaths	12535	00618125102518
20862	TIDIShield Camera Covers with The SureClear Window	12535	00618125102525
20867	TIDIShield Camera Covers with The SureClear Window	12535	00618125102549
20868	TIDIShield Camera Covers with The SureClear Window	12535	00618125102556
20883	TIDIShield Camera Covers with The SureClear Window	12535	00618125109135



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Product Name, Model Number, GMDN, and UDI-DI to which this declaration applies			
Model Number (REF)	Product Name	GMDN	UDI-DI
20884	TIDIShield Camera Covers with The SureClear Window	12535	00618125110742
20893	TIDIShield Intraoral Camera Covers	12535	00618125112906
20905	TIDIShield Camera Covers with The SureClear Window	12535	00618125113385
20909	TIDIShield Camera Covers with The SureClear Window	12535	00618125113897
20911	TIDIShield Camera Covers with The SureClear Window	12535	00618125114832
20916	TIDIShield Camera Covers with The SureClear Window	12535	00618125115808
20917	TIDIShield Camera Covers with The SureClear Window	12535	00618125115839
20929	TIDIShield Camera Covers with The SureClear Window	12535	00618125126163
20932	TIDIShield Camera Covers with The SureClear Window	12535	00618125121014
20933	TIDIShield X-Ray Sensor Sheaths	12535	00618125125616
20935	Camera Covers	12535	00618125127597
20939	TIDIShield Camera Covers with The SureClear Window	12535	00618125130948
20942	TIDIShield Camera Covers with The SureClear Window	12535	00618125155842
20944	Luna HD Sheath	12535	00618125134496
20958	TIDIShield X-Ray Sensor Sheaths	12535	00618125130962
20963	TIDIShield Camera Covers with The SureClear Window	12535	00618125114337
20968	TIDIShield Camera Covers with The SureClear Window	12535	00618125116409
20969	TIDIShield Camera Covers with The SureClear Window	12535	00618125116652
20970	TIDIShield Camera Covers with The SureClear Window	12535	00618125116829
20977	TIDIShield X-Ray Sensor Sheaths	12535	00618125122189
20978	TIDIShield X-Ray Sensor Sheaths	12535	00618125122196
20978F	X-Ray Sensor Sheaths, Carestream Dental LLC Size 1	12535	00618125127610
20979	TIDIShield X-Ray Sensor Sheaths	12535	00618125122202



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Product Name, Model Number, GMDN, and UDI-DI to which this declaration applies			
Model Number (REF)	Product Name	GMDN	UDI-DI
20979F	X-Ray Sensor Sheaths, Carestream Dental LLC Size 2	12535	00618125127634
20980	TIDIShield Camera Covers with The SureClear Window	12535	00618125122233
20981	TIDIShield Camera Covers with The SureClear Window	12535	00618125122240
20987	TIDIShield Camera Covers with The SureClear Window	12535	00618125126392
20990	TIDIShield Camera Covers with The SureClear Window	12535	00618125124497
20999	TIDIShield X-Ray Sensor Sheaths	12535	00618125125692
21001	TIDIShield Camera Covers with The SureClear Window	12535	00618125133062
21002	TIDIShield Camera Covers with The SureClear Window	12535	00618125125548
21013	TIDIShield Camera Covers with The SureClear Window	12535	00618125131082
21014	TIDIShield Camera Covers with The SureClear Window	12535	00618125143887
21019	Polaris Spectra Camera Sheath	12535	618125143887
21020	TIDIShield Intraoral Camera Covers	12535	00618125131433
21022	TIDIShield Camera Covers with The SureClear Window	12535	00618125134793
21026A	TIDIShield Camera Covers with The SureClear Window	12535	00618125161072
6559660 (21036)	TIDIShield Camera Covers with The SureClear Window	12535	00618125131136
6559884 (21038)	TIDIShield Camera Covers with The SureClear Window	12535	00618125131143
21040	TIDIShield X-Ray Sensor Sheaths	12535	00618125133031
21052	TIDIShield X-Ray Sensor Sheaths	12535	00618125160792
21053	TIDIShield X-Ray Sensor Sheaths	12535	00618125160808
21100	TIDIShield Curing Light Sleeves with The SureCure Window	12535	00618125133024
21101	TIDIShield Curing Light Sleeves with The SureCure Window	12535	00618125134243
21102	TIDIShield Curing Light Sleeves with The SureCure Window	12535	00618125134250
21103	TIDIShield Curing Light Sleeves with The SureCure Window	12535	00618125134267





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Product Name, Model Number, GMDN, and UDI-DI to which this declaration applies			
Model Number (REF)	Product Name	GMDN	UDI-DI
21105	TIDIShield Curing Light Sleeves with The SureCure Window	12535	00618125134281
21106	TIDIShield Curing Light Sleeves with The SureCure Window	12535	00618125134298
21107	TIDIShield Curing Light Sleeves with The SureCure Window	12535	00618125134397
21109	TIDIShield Curing Light Sleeves with The SureCure Window	12535	00618125134519
21110	TIDIShield Curing Light Sleeves with The SureCure Window	12535	00618125134519
21113	TIDIShield Curing Light Sleeves with The SureCure Window	12535	00618125177653
21114	TIDIShield Curing Light Sleeves with The SureCure Window	12535	00618125187041
21115	TIDIShield Curing Light Sleeves with The SureCure Window	12535	00618125188833
4665	Disposable Barrier Curing Light Sleeves for Valo X	12535	00618125190188
4666	Disposable Barrier Curing Light Sleeves for Valo Grand	12535	00618125187140
4667	Disposable Barrier Curing Light Sleeves for Valo Cordless	12535	00618125187133
4668	Disposable Barrier Curing Light Sleeves for Valo with Cord	12535	00618125187126
4669	Disposable Barrier Curing Light Sleeves for Valo Grand with Cord	12535	00618125189953
20822	Camera Covers	12535	00618125102303
20926	Protective Covers ERGOcam 4	12535	00618125119202
1006366	Disposable Barrier Curing Light Sleeves for Valo Grand	12535	00618125188710
1006367	Curing Light Sleeves for Valo Cordless Disposable Barrier Sleeves	12535	00618125188727
1006368	Disposable Barrier Curing Light Sleeves for Valo with Cord	12535	00618125188734
1009808	Disposable Barrier Curing Light Sleeves For Valo X	12535	00618125190171
20991	Camera Covers	12535	00618125131013
20976	Camera Covers	12535	00618125122219
20989	Camera Covers	12535	00618125127658






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Product Name, Model Number, GMDN, and UDI-DI to which this declaration applies			
Model Number (REF)	Product Name	GMDN	UDI-DI
21006	Camera Covers	12535	00618125127696
5169110 (20890)	X-Ray Sensor Sheaths Sirona Sensor (2) Sheaths	12535	00618125112463
580649 (20904)	X-Ray Sensor Sheaths Sirona Sensor (1) Sheaths	12535	00618125113309
20900	Camera Covers	12535	00618125113194
20901	Camera Covers	12535	00618125113200
20923	Camera Covers	12535	00618125119004
20965	Camera Covers	12535	00618125115150
20985	Camera Covers	12535	00618125131006
21035	Camera Covers	12535	00618125129072
96829874	Sheath for Oral B Brush	12535	00618125133840
20962	Camera Covers	12535	00618125135301
21054	Camera Covers	12535	00618125143870
D7120	Camera Sheaths	12535	00618125184033
1007218	Curing Light Sleeves for Valo Grand with Cord	12535	00618125188826
20791	Discover Focus Sheath	12535	00618125130153
20820	Patterson Camera Covers (B-80)	12535	00618125102280
20973	Omnia Camera Cover Bulk (B86)	12535	00618125130979
6409952	XIOS XG Hygienic Covers Size 2 (300 p)	12535	00618125155934
6409960	XIOS XG Hygienic Covers Size 0+1 (300 p)	12535	00618125155941
21023	V25SWERV Barrier	12535	00618125142781
20937	Vident 40/Box, 20-Pack/CS	12535	00618125130931
403023 (20936)	Camera Cover (Model B-244)	12535	00618125127634
403017 (20941)	Camera Cover	12535	00618125121083
6149004 (20955)	XIOS Plus Hygienic Covers Size 2 (300 p)	12535	00618125126279
6148998 (20954)	XIOS Plus Hygienic Covers Size 1 (300 p)	12535	00618125126262



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Product Name, Model Number, GMDN, and UDI-DI to which this declaration applies			
Model Number (REF)	Product Name	GMDN	UDI-DI
5914705 (20967)	Camera Cover Fits Sirona SiroCam 3	12535	00618125115259
2108-02108-10-65 (20927)	Intraoral Camera Covers	12535	30618125119210

Product Name	Photo (if appropriate)
Dental Barrier with window	
Curing light sleeves	
Dental Barrier without window	

# EU/UK/AU/CH Declaration of Conformity DC0039 Rev. 13



Glossary of Global Medical Device Nomenclature (GMDN) Terms	
GMDN	Term
12535	Medical equipment drape, single use