EU/UK/AU/CH Declaration of Conformity
DC0039 Rev.16

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

Manufacturer Information:	TIDI Products, LLC 570 Enterprise Drive Neenah, WI 54956 USA SRN: US-MF-000012287
Person Responsible for Regulatory Compliance (PRRC):	Chris Rahn, VP Quality & Regulatory
European Union (EU) Authorized Representative Contact Information:	MDSS GmbH Schiffgraben 41 30175 Hannover Germany Phone (+49) 511 6262 8630 SRN: DE-AR-000005430
United Kingdom (UK) Responsible Person Contact Information:	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
Swiss (CH) Authorized Representative Contact Information:	MDSS CH GmbH Laurenzenvorstadt 61 5000 Aarau Switzerland CHRN: CHRN-AR-20001035.
Product identification:	Instrument Sheaths and Camera Covers (Dental barriers)
Technical File No.:	TF-0019: TIDI Products Dental Barrier Family
Product Model Numbers:	See following page(s) for model numbers, GMDNs, descriptions and photo, where appropriate
EU Legislation and Conformity Assessment Procedure:	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.
UK Legislation and Conformity Assessment Procedure:	UK Medical Devices Regulation 2002 (S1 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).
Australia (AU) Legislation and Conformity Assessment Procedure:	Clause(s) 6.6 of Schedule 3 Part 6 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002
CH Legislation and Conformity Assessment Procedure:	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.

EU/UK/AU/CH Declaration of Conformity
DC0039 Rev.16

Intended purpose:	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.	
EMDN Code:	EMDN (European Medical Device Nomenclature) code for Dental Barriers: • T030202 Camera covers • T030102 Cover sheaths, Instrument, and equipment	
Basic UDI-DI:	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	
Device Classification/ Rule in EU/CH:	Risk Class I	Rule 5
Device Classification/ Rule in UK:	Risk Class I	Rule 5
Device Classification/ Rule in Australia (AU):	Class 1	Rule 3.1
Australian Client ID No.	TIDI's AU Client ID No.: 49283	
Reference to Common Specifications:	NA	
EC Certificate:	EC Number: N/A Self-Declared	Issue Date: N/A Self-Declared
UKCA Certificate:	EC Number: N/A Self-Declared	Issue Date: N/A Self-Declared
Quality Management Certificate - ISO 13485	Number: FM 536366	Effective Date: 29 May 2023
MDSAP Certificate	Number: MDSAP 703786	Effective Date: 29 May 2023
Notified Body for QMS:	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam, The Netherlands NB No. 2797	
Notified Body for EU Conformity Assessment: (*if applicable)*	NA	
Approved Body for UK Conformity Assessment*: (if applicable*)	NA	

EU/UK/AU/CH Declaration of Conformity
DC0039 Rev.16

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 (S1 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 Authorised Representative in Switzerland for the above indicated products.

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

Name of TIDI Representative: Javorka Spalevic	**Title, Function**	**Date**
Approval: Javorka Spalevic	**Approval:** Regulatory Product Manager	10/23/2024

EU/UK/AU/CH Declaration of Conformity
DC0039 Rev.16

Product Name, Model Number, GMDN, and UDI-DI to which this declaration applies.			
Model Number (REF)	**Product Name**	**GMDN**	**UDI-DI**
6554489 (CS1500)	Intraoral Camera Covers	12535	00618125141487
X00128	X-Ray Sensor Sheaths	12535	00618125184002
X00129	X-Ray Sensor Sheaths	12535	00618125184019
20808	Intraoral Camera Covers	12535	00618125133055
20812	Intraoral Camera Covers	12535	00618125102228
20819	X-Ray Sensor Sheaths	12535	00618125102273
20824	X-Ray Sensor Sheaths	12535	00618125102310
20825	X-Ray Sensor Sheaths	12535	00618125102327
20841	X-Ray Sensor Sheaths	12535	00618125102419
20855	Intraoral Camera Covers	12535	00618125102495
20856	Intraoral Camera Covers	12535	00618125102501
20861	X-Ray Sensor Sheaths	12535	00618125102518
20867	Intraoral Camera Covers	12535	00618125102549
20868	Intraoral Camera Covers	12535	00618125102556
20893	Intraoral Camera Covers	12535	00618125112906
20905	Intraoral Camera Covers	12535	00618125113385
20916	Intraoral Camera Covers	12535	00618125115808
20929	Intraoral Camera Covers	12535	00618125126163
20932	Intraoral Camera Covers	12535	00618125121014
20933	X-Ray Sensor Sheaths	12535	00618125125616
20958	X-Ray Sensor Sheaths	12535	00618125130962
20968	Intraoral Camera Covers	12535	00618125116409
20969	Intraoral Camera Covers	12535	00618125116652
20970	Intraoral Camera Covers	12535	00618125116829

EU/UK/AU/CH Declaration of Conformity
DC0039 Rev.16

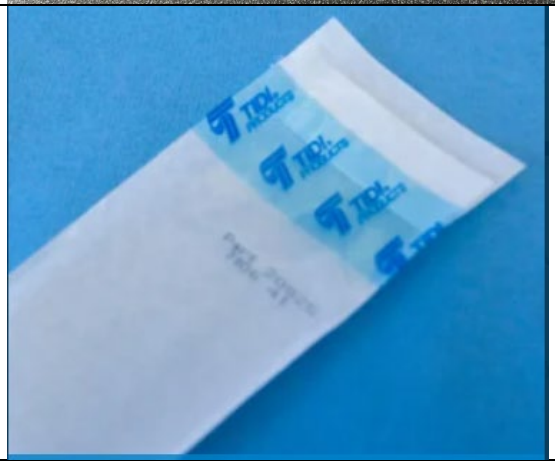
Product Name, Model Number, GMDN, and UDI-DI to which this declaration applies.			
Model Number (REF)	**Product Name**	**GMDN**	**UDI-DI**
20977	X-Ray Sensor Sheaths	12535	00618125122189
20978	X-Ray Sensor Sheaths	12535	00618125122196
20978F	X-Ray Sensor Sheaths	12535	00618125127610
20979	X-Ray Sensor Sheaths	12535	00618125122202
20979F	X-Ray Sensor Sheaths	12535	00618125127634
20981	Intraoral Camera Covers	12535	00618125122240
20987	Intraoral Camera Covers	12535	00618125126392
20990	Intraoral Camera Covers	12535	00618125124497
20999	X-Ray Sensor Sheaths	12535	00618125125692
21001	Intraoral Camera Covers	12535	00618125133062
21013	Intraoral Camera Covers	12535	00618125131082
21019	Polaris Spectra Camera Sheath	12535	618125143887
21020	Intraoral Camera Covers	12535	00618125131433
21022	Intraoral Camera Covers	12535	00618125134793
21026A	Intraoral Camera Covers	12535	00618125161072
6559660 (21036)	Intraoral Camera Covers	12535	00618125131136
6559884 (21038)	Intraoral Camera Covers	12535	00618125131143
21040	X-Ray Sensor Sheaths	12535	00618125133031
21100	Curing Light Sleeves	12535	00618125133024
21101	Curing Light Sleeves	12535	00618125134243
21102	Curing Light Sleeves	12535	00618125134250
21103	Curing Light Sleeves	12535	00618125134267
21105	Curing Light Sleeves	12535	00618125134281
21106	Curing Light Sleeves	12535	00618125134298

EU/UK/AU/CH Declaration of Conformity
DC0039 Rev.16

Product Name, Model Number, GMDN, and UDI-DI to which this declaration applies.			
Model Number (REF)	**Product Name**	**GMDN**	**UDI-DI**
21107	Curing Light Sleeves	12535	00618125134397
21109	Curing Light Sleeves	12535	00618125134519
21110	TIDIShield® Curing Light Sleeves Fits Ivoclar Bluephase G2 and Bluephase 2Oi	12535	00618125134519
21113	TIDIShield® Curing Light Sleeves Fits Ultradent Valo Grand	12535	00618125177653
21114	TIDIShield® Curing Light Sleeves Fits Ultradent Valo with Cord	12535	00618125187041
21115	Curing Light Sleeves	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
(1.002.9067) 20926	Camera Covers	12535	00618125119202
1006366	Disposable Barrier Curing Light Sleeves for Valo Grand	12535	00618125188710
1006367	Disposable Barrier Curing Light Sleeves for Valo Cordless	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
5169110 (20890)	X-Ray Sensor Sheaths	12535	00618125112463
5806497 (20904)	X-Ray Sensor Sheaths	12535	00618125113309
21035	Camera Covers	12535	00618125129072
20962	Camera Covers	12535	00618125135301
21054	Camera Covers	12535	00618125143870

EU/UK/AU/CH Declaration of Conformity
DC0039 Rev.16

Product Name, Model Number, GMDN, and UDI-DI to which this declaration applies.			
Model Number (REF)	**Product Name**	**GMDN**	**UDI-DI**
D7120	Camera Sheaths	12535	00618125184033
1007218	Disposable Barrier Curing Light Sleeves for Valo Grand with Cord	12535	00618125188826
6409952	XIOS XG S2 Sheath	12535	00618125155934
6409960	XIOS XG S0 and S1 Sheath	12535	00618125155941
403023 (20936)	Intraoral Camera Covers	12535	00618125127634
403017 (20941)	Intraoral Camera Covers	12535	00618125121083
6149004 (20955)	XIOS+ SHEATH SIZE 2	12535	00618125126279
6148998 (20954)	XIOS+ SHEATH SIZE 1	12535	00618125126262
5914705 (20967)	Camera Cover	12535	00618125115259
2108-02108-10-65 (20927)	Intraoral Camera Covers	12535	30618125119210

Product Name	**Photo (if appropriate)**
Curing Light Sleeves	
Intraoral Camera Covers	

EU/UK/AU/CH Declaration of Conformity
DC0039 Rev.16

X-ray Sensor Sheaths	

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