



# Declaration of Conformity DC0039 Rev. 02

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

<b>Manufacturer Information Name, Address, SRN:</b>	TIDI Products, LLC 570 Enterprise Drive Neenah, WI 54956 USA	SRN:  TBD
<b>Name of responsible person (PRRC) or designee:</b>	Name: Steve Kahn	Title: VP of Quality and Regulatory
<b>Authorized Representative Contact Information:</b>	Medical Device Safety Service GmbH Schiffgraben 41 30175 Hannover Germany	SRN:  DE-AR-000005430
<b>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>Technical File No.:</b>	TF-0019: TIDI Products Dental Barrier Family	
<b>Product Identification:</b>	Instrument Sheaths and Camera Covers (Dental barriers)	
<b>Product Model Numbers:</b>	See following page(s) for model numbers, GMDNs, descriptions and photo, where appropriate	
<b>Basic UDI-DI/ Intended purpose:</b>	<p>The dental barriers family of devices are intended for use in the general population. The intended use is for use as a barrier that is 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. The devices are non-sterile and intended for single patient use only. Indications include using as a barrier on; intra-oral cameras, thermometers, X-Ray sensors, bite blocks, LED curing lights, carries detection instruments and reusable hand-held dental equipment in general.</p> <p>Basic UDI-DI for dental barriers:</p> <p>Curing Light sleeves    0618125TF-0019-AXS            Camera Covers        0618125TF-0019-BXU            X-ray sensor sheaths   0618125TF-0019-CXW            General                 0618125TF-0019-DXY</p>	
<b>Device Classification/Rule:</b>	Risk Class I	Rule 5
<b>Reference to Common Specifications:</b>	N/A	
<b>EC Certificate:</b> <i>If self-declared add "N/A Self-Declared".</i>	EC Number: N/A Self-Declared	Issue Date: N/A Self-Declared



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<b>Quality Management Certificate:</b>	Number: FM 536366	Issue Date: 29 May 2020
<b>Notified Body Information for QMS:</b>	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands	
<p>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.</p>		
<b>Signed for on behalf of TIDI Products LLC, in Neenah, WI.</b>		
<b>Name of Authorized Person:</b>	<b>Title:</b>	<b>Date:</b>
<b>Approval:</b> <i>Javoroka Spalevic</i>	Sr. Regulatory Affairs Specialist	17 Aug 2021



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Model Number (REF)	Product Name	GMDN	UDI-DI
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
20521	Oral Disposable Thermometer Sheaths	12535	00618125101641
20524	Oral Disposable Thermometer Sheaths	12535	00618125101658
20710	TIDIShield Camera Covers with The SureClear Window	42391	00618125115389
20800	TIDIShield Camera Covers with The SureClear Window	12535	00618125115389
20802	TIDIShield Camera Covers with The SureClear Window	12535	00618125102181
20805	TIDIShield Camera Covers with The SureClear Window	12535	00618125102204
20806	TIDIShield Camera Covers with The SureClear Window	12535	00618125114252
20808	TIDIShield Camera Covers with The SureClear Window	12535	00618125133055
20810	TIDIShield Camera Covers with The SureClear Window	12535	00618125102211
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
20829	TIDIShield Camera Covers with The SureClear Window	12535	00618125102334
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
20852	TIDIShield Camera Covers with The SureClear Window	12535	00618125102488
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



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Model Number (REF)	Product Name	GMDN	UDI-DI
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
20876	TIDIShield Camera Covers with The SureClear Window	12535	00618125108992
20883	TIDIShield Camera Covers with The SureClear Window	12535	00618125109135
20884	TIDIShield Camera Covers with The SureClear Window	12535	00618125110742
20893	TIDIShield Intraoral Camera Covers	12535	00618125112906
20899	TIDIShield Camera Covers with The SureClear Window	12535	00618125113101
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
20915	TIDIShield Camera Covers with The SureClear Window	12535	00618125115785
20916	TIDIShield Camera Covers with The SureClear Window	12535	00618125115808
20917	TIDIShield Camera Covers with The SureClear Window	12535	00618125115839
20927	Acclaim Camera Sheath	12535	00618125119219
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
20934	TIDIShield X-Ray Sensor Sheaths	12535	00618125125609
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
20957	TIDIShield X-Ray Sensor Sheaths	12535	00618125130955
20958	TIDIShield X-Ray Sensor Sheaths	12535	00618125130962
20963	TIDIShield Camera Covers with The SureClear Window	12535	00618125114337
20964	TIDIShield Camera Covers with The SureClear Window	12535	00618125114788



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Model Number (REF)	Product Name	GMDN	UDI-DI
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
20977F	X-Ray Cover	12535	00618125123537
20978	TIDIShield X-Ray Sensor Sheaths	12535	00618125122196
20978F	X-Ray Cover	12535	00618125127610
20979	TIDIShield X-Ray Sensor Sheaths	12535	00618125122202
20979F	X-Ray Cover	12535	00618125127634
20980	TIDIShield Camera Covers with The SureClear Window	12535	00618125122233
20981	TIDIShield Camera Covers with The SureClear Window	12535	00618125122240
20984	TIDIShield Camera Covers with The SureClear Window	12535	00618125122493
20987	TIDIShield Camera Covers with The SureClear Window	12535	00618125126392
20990	TIDIShield Camera Covers with The SureClear Window	12535	00618125124497
20993	TIDIShield Camera Covers with The SureClear Window	12535	00618125131020
20998	TIDIShield X-Ray Sensor Sheaths	12535	618125125548
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
21003	DEXcam 3 Intra-Oral Camera Sheaths	12535	00618125131044
21004	Intraoral Camera Sheaths	12535	00618125130290
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
21021	TIDIShield Camera Covers with The SureClear Window	12535	00618125155866
21022	TIDIShield Camera Covers with The SureClear Window	12535	00618125134793
21025	DEXIS Intra-oral Camera Sheaths	12535	00618125155873
21026A	TIDIShield Camera Covers with The SureClear Window	12535	00618125161072
21036	TIDIShield Camera Covers with The SureClear Window	12535	00618125131136



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Model Number (REF)	Product Name	GMDN	UDI-DI
21038	TIDIShield Camera Covers with The SureClear Window	12535	00618125131143
21040	TIDIShield X-Ray Sensor Sheaths	12535	00618125133031
21041	TIDIShield X-Ray Sensor Sheaths	12535	00618125133048
21052	TIDIShield X-Ray Sensor Sheaths	12535	00618125160792
21053	TIDIShield X-Ray Sensor Sheaths	12535	00618125160808
21058	TIDIShield X-Ray Sensor Sheaths	12535	00618125160884
21059	TIDIShield X-Ray Sensor Sheaths	12535	00618125160891
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
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
4666	Disposable Barrier Curing Light Sleeves for Valo Grand	12535	00618125187140
4667	Disposable Barrier Curing Light Sleeves for Valo Grand	12535	00618125187133
4668	Curing Light with Cord	12535	00618125187126
4669	Curing Light Sleeve for Valo Grand with Cord	12535	00618125189953
20936	Camera Covers	12535	00618125130924
20817	Instrument Sheaths	12535	00618125114849
20844	Instrument Sheaths	12535	00618125102426
20822	Camera Covers	12535	00618125102303
20926	Protective Covers ERGOcam 4	12535	00618125119202
20941	Camera Covers	12535	00618125121083
1006366	Curing Light Sleeves for Valo Grand Disposable Barrier Sleeves	12535	00618125188710









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Model Number (REF)	Product Name	GMDN	UDI-DI
1006367	Curing Light Sleeves for Valo Cordless Disposable Barrier Sleeves	12535	00618125188727
1006368	Curing Light Sleeves for Valo Disposable Barrier Sleeves	12535	00618125188734
20991	Camera Covers	12535	00618125131013
20538	Oral Disposable Thermometer Sheaths	42391	00618125101719
20542	Oral Disposable Thermometer Sheaths	42391	00618125101726
20631	Oral Disposable Thermometer Sheaths	13116	00618125101863
20674	Oral Disposable Thermometer Sheaths	13116	00618125102037
20706	Rectal Disposable Thermometer Sheaths	13116	00618125114399
20720	Rectal Disposable Thermometer Sheaths	42391	00618125102136
20835	Rectal Disposable Thermometer Sheaths	13116	00618125102372
20976	Camera Covers	12535	00618125122219
20989	Camera Covers	12535	00618125127658
21006	Camera Covers	12535	00618125127696
20997	X-Ray Cover	12535	00618125125623
20890	Sensor (2) Sheaths	12535	00618125112463
20904	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
CA0007	Borea Tooth Shade Scanner Sheath	12535	00618125183951
D7120	Camera Sheaths	12535	00618125184033
20536	Oral Disposable Thermometer Sheaths	42391	00618125101696
1007218	Curing Light Sleeve 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
21058A	Tuxedo Sheath Start Kit SZ1	12535	00618125160716
6409952	SHTH XIOS XG Select S2 B249	12535	00618125155934
6409960	SHTH Schick XIOS XG S1 B235	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)	X-Ray Sensor Sheath Sirona XIOS Plus Size 2	12535	00618125126279
6148998 (20954)	X-Ray Sensor Sheath Sirona XIOS Plus Size 1	12535	00618125126262
59 14 705 (20967)	Hygienic Protection Sheaths for Sirocam C	12535	00618125115259

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Product Name	Photo (if appropriate)
Dental Barrier with window	
Dental Barrier without window	
Curing light sleeves	
X-ray sensor sheaths	





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<b>GMDN</b>	<b>Term</b>
12535	Medical equipment drape, single use
13116	Electronic thermometer probe cover
42391	Capillary thermometer cover