


**MANUFACTURER**

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**Declaration of Conformity  
 As per Annex IV MDR (EU) 2017/745**

**To:** We the Manufacturer declare, under our sole responsibility that the products described below to which the Technical Documentation applies, complies with the applicable provisions of the General Safety and Performance requirements as per Annex I and the classification rules as per Annex VIII during the life time of the product.

Our Quality Management System has been prepared in accordance with ISO13485: 2016, FDA 21 CFR Part 820 and Annex IX Chapter I and our Technical Documentation in accordance with Annex IX Chapter II of the MDR (EU) 2017/745. The use of the following Harmonized standards: EN ISO 14971: 2019, BS EN ISO 15223-1: 2021, IEC 62336-1: 2015, ISO 10993-10: 2021 & BS EN ISO 7405: 2018, ISO 20417: 2021 and ISO 11737-2: 2019

<b>Device Name:</b>	<b>Common Details</b>
1- Classification & Common Name: 2- Trade/Proprietary Name	1- Orthodontic Hand Instruments 2- Aligner Pliers, Beck Premium Cutters™, Bracket Placers & Tweezers, Mathieu pliers, Razor Premium Cutting Pliers™, Spectrum pliers™
3- Materials	3- Stainless steel
4- MDS & MDT Codes:	4- MDS – 1006, MDT 2013, 2001
5- Basic UDI-DI (HIBCC)	5-(Attachment below) ++D909TCFHI7H
6 – EMDN Code: L99	6 – Reusable Hand Instruments - Other
<b>Note:-</b> List of actual devices covered under this declaration are attached	

**As per MDR (EU) 2017/745 Annex VIII our devices have a “Risk Classification” I as per rule 5**

<b>Authorized European Representative As per Annex IX Chapter III</b>	<b>Certification Body</b>
<b>Emergo Europe BV</b> Westervoortsedijk 60 6827 AT Arnhem The Netherlands Tel: +31 (0) 70 345 8570	<b>BSI Group America, Inc.</b> 12950 Worldgate Drive, Suite 800 Herndon, VA 20170-6007 USA
<b>Note:</b> The Technical file is maintained at the manufactures location and an agreement is in place with our Authorized EU Rep to share information along with reporting requirements	<b>Certificate Numbers</b> EC Certificate – Production Quality Assurance Certificate No. FM 668843 Expiration: 2024-01-04

**\*Note: List of actual devices covered under this declaration are attached.**



**President**  
**Name: Doug Bukaty**

**Date 2025 August 27<sup>th</sup>**



**Regulatory Manager**  
**Jonathan Leng**

**Date 2025 August 27<sup>th</sup>**

Product Code	Description	GMDN	FDA Code	UDI-DI
550-001	ASHER FACEBOW UPPER	40468	EIG	+D9095500010/
550-002	ASHER FACEBOW LOWER	40468	EIG	+D9095500020
550-100	MULTI ADJUSTABLE FACEMASK BLUE	41067	EIG	+D9095501000/
550-101	MULTI ADJUSTABLE FACEMASK RED	41067	EIG	+D9095501010
550-102	MULTI ADJUSTABLE FACEMASK PEARL	41067	EIG	+D9095501020%
550-103	MULTI ADJUSTABLE FACEMASK CLEAR	41067	EIG	+D90955010300
600-032	DOUBLE ENDED LIP RETRACTORS - ADULT/TEEN (2)	13380	EIG	+D9096000320/
600-033	DOUBLE ENDED LIP RETRACTORS - CHILD (2)	13380	EIG	+D9096000330
600-034	PHOTO LIP RETRACTOR - 45 DEGREE HANDLE (LARGE)	13380	EIG	+D90960003410
600-035	PHOTO LIP RETRACTOR - 45 DEGREE HANDLE (SMALL)	13380	EIG	+D90960003511
600-049	EXPANDO CHEEK RETRACTOR ASSORTMENT (3)	13380	EIG	+D90960004916
600-050	EXPANDO CHEEK RETRACTORS ADULT (2)	13380	EIG	+D9096000501
600-051	EXPANDO CHEEK RETRACTORS PEDO (2)	13380	EIG	+D9096000511%
600-052	EXPANDO CHEEK RETRACTORS TEEN (2)	13380	EIG	+D90960005221
600-751	ACCESS CHEEK RETRACTOR PEDO	13380	EIG	+D90960075116
600-752	ACCESS CHEEK RETRACTOR ADULT	13380	EIG	+D90960075217
600-753	LIP RETRACTOR	13380	EIG	+D90960075318
700-600	PRE-ORTHODONTIC TRAINER T4K STARTER BLUE	17802	ECP	+D90970060010
700-601	PRE-ORTHODONTIC TRAINER T4K STARTER GREEN	17802	ECP	+D90970060111
700-602	PRE-ORTHODONTIC TRAINER T4K FINISHER	17802	ECP	+D90970060212
700-603	PRE-ORTHODONTIC TRAINER FOR BRACES T4B	17802	ECP	+D90970060313
700-604	CLASS II T4K TRAINER	17802	ECP	+D90970060414
700-605	T.M.J. APPLIANCE	17802	ECP	+D90970060515
700-606	T4 SILICONE TRAINER ( GREEN)	17802	ECP	+D90970060616
700-609	PHASE I TRAINER PINK	17802	ECP	+D90970060919
700-610	T4A PHASE I BLUE	17802	ECP	+D90970061011
700-611	INFANT TRAINER PHASE I	17802	ECP	+D90970061112
700-612	INFANT TRAINER PHASE II	17802	ECP	+D90970061213
700-613	FUNCTIONAL TRAINER	17802	ECP	+D90970061314
700-617	T4A PHASE II RED	17802	ECP	+D90970061718
711-202	Plain Face Bow W/ SHORT Outer Bow	40468	EIG	+D90971120210
800-001	SPECTRUM LIGHT WIRE PLIERS / LONG BIRD BEAK	33209	JEX	+D9098000011
800-002	SPECTRUM BIRD BEAK PLIERS W/ CUTTER	33209	JEX	+D9098000021
800-003	SPECTRUM BIRD BEAK PLIERS	33209	JEX	+D9098000031
800-004	SPECTRUM WEINGART UTILITY PLIERS	33209	JEX	+D9098000041
800-005	SPECTRUM BIRD BEAK PLIERS W/ GROOVES	33209	JEX	+D9098000051
800-005M	SPECTRUM CONLIN LW PLIER WITHOUT NOTCH	33209	JEX	+D909800005M1
800-006	SPECTRUM SAFETY HOLD DISTAL END CUTTER - LONG HANDLE	32885	HXZ	+D9098000061
800-007	SPECTRUM FLAT ON FLAT PLIERS	33209	JEX	+D9098000071
800-008	SPECTRUM V-BEND STOP PLIERS	33209	JEX	+D9098000081
800-009	SPECTRUM POSTERIOR BAND REMOVER	63677	JEX	+D9098000091
800-009T	SPECTRUM POSTERIOR BAND REMOVER - TIPS (3)	63677	JEX	+D909800009T2
800-010	DELUXE ELASTIC SEPARATING PLIER	33209	JEX	+D9098000101
800-012	SPECTRUM THREE PRONG PLIERS	33209	JEX	+D9098000121
800-014	SPECTRUM SAFETY HOLD DISTAL END CUTTER	32885	HXZ	+D9098000141
800-015	SPECTRUM SAFETY HOLD DISTAL END CUTTER - FLUSH CUT	32885	HXZ	+D9098000151
800-016	SPECTRUM PIN & LIGATURE CUTTER	32885	HXZ	+D9098000161
800-0163	SPECTRUM MINI LIGATURE CUTTER	32885	HXZ	+D90980001631
800-0164	MICRO LIGATURE CUTTER - CURVED***DISCONTINUED/ WHILE SUPPLIES LAST. NON-REFUNDABLE OR RETURNABLE***	32885	HXZ	+D90980001641
800-0165	MICRO LIGATURE CUTTER - STRAIGHT***DISCONTINUED/ WHILE SUPPLIES LAST. NON-REFUNDABLE OR RETURNABLE***	32885	HXZ	+D90980001651
800-017	SPECTRUM JARABAK PLIERS	33209	JEX	+D9098000171
800-018	BAND SEATER/ BITE STICK - HI HEAT ***DISCONTINUED/ WHILE SUPPLIES LAST. NON-REFUNDABLE OR RETURNABLE***	31801	ECP	+D9098000181
800-0182	BAND SEATER/ BITE STICK - AUTOCLAVABLE	31801	ECP	+D90980001821
800-022	SPECTRUM DISTAL NITI WIRE CRIMPER	33209	JEX	+D9098000221
800-022S	SPECTRUM MINI DISTAL NITI WIRE CRIMPER***DISCONTINUED/ WHILE SUPPLIES LAST. NON-REFUNDABLE OR RETURNABLE***	33209	JEX	+D909800022S1
800-023	SPECTRUM HARD WIRE CUTTER	32885	HXZ	+D9098000231
800-027	KEAT MOLAR TUBE PLACER - LONG HANDLE	35420	ECP	+D9098000271
800-028	KEAT MOLAR TUBE PLACER	35420	ECP	+D9098000281
800-029	CLASS II PLACEMENT INSTRUMENT	35421	ECP	+D90980002916
800-030	DELUXE BRACKET PLACER/ SLOT ALIGNER	35420	ECP	+D9098000301
800-031	ANTERIOR BRACKET PLACER	35420	ECP	+D9098000311
800-032	CONLIN BRACKET PLACER	35420	ECP	+D9098000321
800-033	SPECTRUM HEAVY DUTY CUTTER (up to .060)	32885	HXZ	+D9098000331
800-034	BOONE BRACKET GAUGE	37419	EIL	+D9098000341
800-035	SPECTRUM HOLLOW CHOP PLIERS	33209	JEX	+D9098000351
800-036	SPECTRUM HOWE UTILITY PLIERS - CURVED	33209	JEX	+D9098000361
800-038	SPECTRUM HOWE UTILITY PLIERS - STRAIGHT	33209	JEX	+D9098000381
800-039L	REVERSE ACTION KEAT MOLAR TUBE PLACER - LONG HANDLE	35420	ECP	+D909800039L1
800-040	BRACKET PLACING TWEEZERS	35420	ECP	+D9098000401
430-028	SLIDING ARCHWIRE LOCK DBL ENDED WRENCH	35420	ECP	+D90943002814
800-041	5 IN 1 BRACKET PLACER & ALIGNER	35420	ECP	+D9098000411
800-043	SPECTRUM TWEED RIBBON ARCH FORMING PLIERS	33209	JEX	+D9098000431
800-044	SPECTRUM TWEED LOOP FORMING PLIERS	33209	JEX	+D9098000441

Product Code	Description	GMDN	FDA Code	UDI-DI
800-045	COTTON TWEEZER/ SLOT ALIGNER	35420	ECP	+D9098000451
800-046	MOLAR DIRECT BOND BRACKET POSITIONER	35420	ECP	+D9098000461
800-048	HEAVY BAND PUSHER	31801	ECP	+D9098000481
800-050	LARGE MOUTH MIRROR	31776	EAX	+D9098000501
800-050M	LARGE MOUTH MIRROR - MAGNIFIED****DISCONTINUED ITEM, WHILE SUPPLIES LAST****	31776	EAX	+D909800050M1
800-061	SPECTRUM OPTICAL PLIER (OCCULIST)	33209	JEX	+D9098000611
800-062	LITE 1/4' DBL ENDED LIGATURE DIRECTOR - BLUE HANDLE	37413	ECP	+D9098000621
800-062W	LITE 3/8' DBL ENDED LIGATURE DIRECTOR	37413	ECP	+D909800062W1
800-063	SPECTRUM DIRECT BOND BRACKET REMOVER - ANGLED	33209	JEX	+D9098000631
800-063A	SPECTRUM ANTERIOR BRACKET REMOVER	33209	JEX	+D909800063A1
800-063C	SPECTRUM DEBONDING PLIERS ANGLED ***discontinued*****	33209	JEX	+D909800063C1
800-063L	DIRECT BOND BRACKET REMOVER - LONG HANDLE***DISCONTINUED/ WHILE SUPPLIES LAST. NON-REFUNDABLE OR RETURNABLE***	33209	JEX	+D909800063L1P
800-064	LITE 1/4' BAND PUSHER/ SCALER - BLUE HANDLE	37413	ECP	+D9098000641
800-064W	LITE 3/8' BAND PUSHER/ SCALER	37413	ECP	+D909800064W1
800-064X	LITE 1/4' BAND PUSHER/ SCALER ***DISCONTINUED/ WHILE SUPPLIES LAST. NON-REFUNDABLE OR RETURNABLE***	37413	ECP	+D909800064X1
800-065	LITE 1/4' LIGATURE REMOVER/ DIRECTOR - BLUE HANDLE	37413	ECP	+D9098000651
800-065W	LITE 3/8' LIGATURE REMOVER/ DIRECTOR	37413	ECP	+D909800065W1
800-065X	LITE 1/4' LIGATURE REMOVER/ DIRECTOR ***DISCONTINUED/ WHILE SUPPLIES LAST. NON-REFUNDABLE OR RETURNABLE***	37413	ECP	+D909800065X1\$
800-066	BRACKET HEIGHT GAUGE - .018	37419	EIL	+D9098000661
800-067	BRACKET HEIGHT GAUGE - .022	37419	EIL	+D9098000671
800-068	SWIVEL HEAD BRACKET HEIGHT GAUGE	37419	EIL	+D9098000681
800-069	DBL ENDED ELASTIC REMOVER - BLUE HANDLE	33209	JEX	+D9098000691
800-070	MOSQUITO HEMOSTAT - REGULAR TIP***DISCONTINUED/ WHILE SUPPLIES LAST. NON-REFUNDABLE OR RETURNABLE***	38791	ECP	+D90980007012
800-070C	MOSQUITO HEMOSTAT - CURVED	38791	ECP	+D909800070C1
800-070W	MOSQUITO HEMOSTAT - FINE TIP	38791	ECP	+D909800070W1
800-071	PRECISION LIGATURE DIRECTOR - BLUE HANDLE	37413	ECP	+D9098000711
800-072	Ligature Director/Scaler/ Elastomeric Tie Remover ***DISCONTINUED/ WHILE SUPPLIES LAST. NON-REFUNDABLE OR	33209	JEX	+D90980007214
800-073	POLAR BEAR MARTENSITIC POSITIONER	37413	ECP	+D9098000731
800-074	SPECTRUM ADHESIVE REMOVER	33209	JEX	+D9098000741
800-075	CINCH BACK/ DISTAL BENDER - BLUE HANDLE	37413	ECP	+D909800074B1
800-076	BRACKETIZER - BLUE HANDLE	37413	ECP	+D909800074P2
800-077	MATHIEU NEEDLE HOLDER - ULTRA FINE TIP (Curved)	12726	ECP	+D90980007719
800-078	LITE 3/8' DBL ENDED SLB BRACKET WIRE DIRECTOR/ OPENING TOOL - BLUE HANDLE	62086	ECP	+D9098000781
800-081	DELUXE BOLEY GAUGE CURVED	37419	EIL	+D90980008114
800-081C	BOLEY GAUGE CURVED ***DISCONTINUED/ WHILE SUPPLIES LAST. NON-REFUNDABLE OR RETURNABLE***	37419	EIL	+D909800081C1G
800-083N	SPECTRUM ULTIMATE HOOK CRIMPING PLIER	33209	JEX	+D909800083N1*
800-084	SPECTRUM STOP CRIMPING PLIER***DISCONTINUED/ WHILE SUPPLIES LAST. NON-REFUNDABLE OR RETURNABLE***	33209	JEX	+D90980008417
800-085	SPECTRUM POSTERIOR HOOK CRIMPING PLIER***DISCONTINUED/ WHILE SUPPLIES LAST. NON-REFUNDABLE OR RETURNABLE*	33209	JEX	+D90980008518
800-087	SPECTRUM GTS CRIMPING PLIER	33209	JEX	+D9098000871
800-088	SPECTRUM LOOP TIE BACK PLIER	33209	JEX	+D9098000881
800-106	CLEAR-LOCK CERAMIC OPENING TOOL	62086	ECP	+D90980010612
800-117	MATHIEU NEEDLE HOLDER W/ SAFETY LATCH - HOLE TIP	12726	ECP	+D90980011714
800-118	MATHIEU NEEDLE HOLDER W/ SAFETY LATCH - FLAT TIP ***DISCONTINUED****	12726	ECP	+D90980011815
800-119	MATHIEU NEEDLE HOLDER W/ SAFETY LATCH - HOOK TIP	12726	ECP	+D90980011916
800-120	MATHIEU NEEDLE HOLDER W/ SAFETY LATCH - FINE TIP	12726	ECP	+D9098001201+
800-121	MATHIEU NEEDLE HOLDER W/ SAFETY LATCH - ULTRA FINE TIP	12726	ECP	+D90980012119%
800-122	MATHIEU NEEDLE HOLDER W/ SAFETY LATCH - REGULAR TIP	12726	ECP	+D90980012210
800-123	SPECTRUM UTILITY ARCH PLIER	33209	JEX	+D9098001231
800-124	SPECTRUM ANGLED UTILITY ARCH PLIER	33209	JEX	+D9098001241
800-125	SPECTRUM UTILITY ARCH 3MM STEP PLIER	33209	JEX	+D9098001251
800-126	SLB OPENING TOOL	62086	ECP	+D90980012614
800-127	SPECTRUM THREE PRONG CLASP PLIER	33209	JEX	+D9098001271
800-128	SPECTRUM LOOP FORMING & CLOSING PLIER	33209	JEX	+D9098001281
800-129	SPECTRUM LINGUAL ARCH FORMING PLIER	33209	JEX	+D9098001290
800-130	SPECTRUM TORQUING PLIER SET W/ WIDE KEY	33209	JEX	+D9098001302
800-132	SPECTRUM THREE PRONG FACEMASK/ FACEBOW PLIER	33209	JEX	+D9098001311
800-133	SHORTY TWIST HOLDER	33209	ECP	+D90980013312
800-136	VANISH SLB OPENING & CLOSING TOOL	62086	ECP	+D90980013615
800-137	DELUXE GRAM GAUGE (600 GRAMS)	37419	EIL	+D90980013716
800-138	SPECTRUM BONDED APPLIANCE REMOVER WITH SWIVEL	63677	JEX	+D90980013817
800-139	IPR GAUGE	37419	EIL	+D90980013918
800-140	ANDERSON GAUGE	37419	EIL	+D90980014010
800-141	SLB MOLAR OPENING TOOL	62086	ECP	+D90980014111
800-146	ECLIPSE SLB OPENING TOOL	62086	ECP	+D90980014616
800-147	ECLIPSE SLB CLOSING TOOL	62086	ECP	+D90980014717
800-148	ECLIPSE SLB CLOSING TOOL W/ WIRE DIRECTOR	62086	ECP	+D90980014818
800-151	ALIGNER PLIERS - HOLE PUNCH	33209	JEX	+D90980015112
800-152	ALIGNER PLIERS - HORIZONTAL PUNCH	33209	JEX	+D90980015213
800-153	ALIGNER PLIERS - VERTICAL PUNCH	33209	JEX	+D90980015314
800-154	ALIGNER PLIERS - TEAR DROP HOLE	33209	JEX	+D90980015415
800-155	ALIGNER PLIERS - DIMPLE PUNCH	33209	JEX	+D90980015516
800-156	ALIGNER PLIERS - DIMPLE ERASER	33209	JEX	+D90980015617
800-213	RAZOR DISTAL END SAFETY CUTTER - LONG HANDLE	32885	HXZ	+D90980021311

Product Code	Description	GMDN	FDA Code	UDI-DI
800-214	RAZOR DISTAL END SAFETY CUTTER	32885	HXZ	+D90980021412
800-215	RAZOR DISTAL END SAFETY CUTTER - FLUSH CUT	32885	HXZ	+D90980021513
800-217	RAZOR PIN & LIGATURE CUTTER MINIATURE	32885	HXZ	+D90980021715
800-218	RAZOR PIN & LIGATURE CUTTER SLIM	32885	HXZ	+D90980021816
800-219	RAZOR PIN & LIGATURE CUTTER - FINE TIP	32885	HXZ	+D90980021917
800-223	RAZOR HARD WIRE CUTTER	32885	HXZ	+D90980022312
800-230	RAZOR WEINGART PLIER	33209	JEX	+D90980023010
800-231	RAZOR TWEED ARCH BENDING PLIER	33209	JEX	+D90980023111
800-232	RAZOR JARABAK PLIER	33209	JEX	+D90980023212
800-233	RAZOR LOOP FORMING PLIER	33209	JEX	+D90980023313
800-234	RAZOR OPTICAL PLIER	33209	JEX	+D90980023414
800-235	RAZOR BIRD BEAK PLIER	33209	JEX	+D90980023515
800-236	RAZOR LIGHT WIRE PLIER	33209	JEX	+D90980023616
800-237	RAZOR THREE PRONG PLIER	33209	JEX	+D90980023717
800-238	RAZOR CINCH BACK PLIER	33209	JEX	+D90980023818
800-239	RAZOR POSTERIOR BAND REMOVER	33209	JEX	+D90980023919
800-239T	RAZOR POSTERIOR BAND REMOVER TIPS (3)	33209	JEX	+D909800239T1
800-240	RAZOR HOLLOW CHOP ARCH FORMING PLIER	33209	JEX	+D90980024011
800-241	RAZOR BRACKET REMOVING PLIER	33209	JEX	+D90980024112
800-242	RAZOR DIRECT BOND BRACKET REMOVER - ANGLED	33209	JEX	+D90980024213
800-276	STEP PLIER 1MM	33209	JEX	+D9098002761A
800-277	STEP PLIER 3/4MM	33209	JEX	+D9098002771B
800-278	STEP PLIER 1/2MM	33209	JEX	+D9098002781C
800-279	Step Plier 1/4MM ***DISCONTINUED/ WHILE SUPPLIES LAST. NON-REFUNDABLE OR RETURNABLE***	33209	JEX	+D9098002791D
800-510	MINI CURING LIGHT	35775	ECP	+D90980051011
800-511	REDI SET LED LIGHT	35775	ECP	+D90980051112
801-020	PHOTOGRAPHIC MIRRORS ADULT OCCLUSAL/CHILD OCCLUSAL	31776	EAX	+D9098010201+
801-021	PHOTOGRAPHIC MIRRORS BUCCAL LATERAL	31776	EAX	+D9098010211%
801-022	PHOTOGRAPHIC MIRRORS ADULT OCCLUSAL/CHILD OCCLUSAL	31776	EAX	+D90980102210
801-023	PHOTOGRAPHIC MIRRORS ADULT BUCCAL/ADULT OCCLUSAL	31776	EAX	+D90980102311
801-024	PHOTOGRAPHIC MIRRORS LINGUAL UPPER/LINGUAL LOWER	31776	EAX	+D90980102412
801-025	PHOTOGRAPHIC MIRRORS CHILD BUCCAL/ADULT OCCLUSAL	31776	EAX	+D90980102513
801-026	PHOTOGRAPHIC MIRRORS CHILD OCCLUSAL/CHILD BUCCAL	31776	EAX	+D90980102614
801-031	SUPER GLASS MIRROR - OCCLUSAL	31776	EAX	+D9098010301%
801-032	SUPER GLASS MIRROR - LINGUAL	31776	EAX	+D90980103110
801-033	SUPER GLASS MIRROR - BUCCAL	31776	EAX	+D90980103211
900-201	COTTON MOUTH BITE BLOCK	44828	DYN	+D9098002011%