

EN - Declaration of Conformity

We, the manufacturer,

Key Surgical LLC
8101 Wallace Rd.
Eden Prairie, MN 55344
USA

ensure and declare with sole responsibility, that the following Class I non-sterile (per MDR), non- reusable, non-measuring medical devices meet the provisions of the EU Medical Device Regulation 2017/745 (MDR) Annex IV for Medical Devices, which apply to them. These devices are in conformity to the Medical Device Regulation 2017/745 that provides for the issuing of the EU declaration of conformity. All supporting documentation is retained under the premises of the manufacturer.

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
Cleaning Brushes Intended Purpose: Cleaning of medical devices	Key Surgical Burr Brushes	BR-1010, BR-1031, BR-1033, BR-1050, BR-1010-50, BR-1031-50, BR-1033-50, BR-1050-50	UMDNS: 10-502 GMDN: 38835	084977100000000000000001M3	There are no common specifications set forth by the European Commission under MDR that apply to Key Surgical product in this Declaration. Applied recognized standards are identified in technical documentation.
	Key Surgical Instrument and Channel Cleaning Brushes	26481	UMDNS: 21-134 GMDN: 34878 & 38835		
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		AT-18-375			
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		AT-24-062			

		AT-24-062-50 AT-24-087 AT-24-087-50 AT-24-105 AT-24-105-50 AT-24-118 AT-24-118-50 AT-24-125 AT-24-125-50 AT-24-131 AT-24-131-50 AT-24-158 AT-24-158-50 AT-24-197 AT-24-197-50 AT-24-250 AT-24-250-50 AT-24-276 AT-24-276-50 AT-24-375 AT-24-375-50 AT-24-440 AT-24-440-50 B-2100-50 BBR001 BBR002 BBR003 BR-04-003 BR-04-003-50 BR-04-080 BR-04-080-50 BR-06-039-50 BR-06-062 BR-06-062-50 BR-06-079 BR-06-079-50 BR-06-250 BR-06-250-50 BR-06-375 BR-06-375-50 BR-06-500 BR-06-500-50 BR-07-075 BR-07-075-50 BR-07-107 BR-07-107-50 BR-08-039 BR-08-039-50 BR-08-070 BR-08-070-50 BR-08-079 BR-08-079-50 BR-08-087 BR-08-087-50 BR-08-092 BR-08-092-50 BR-08-105 BR-08-105-50 BR-08-118 BR-08-118-50 BR-08-131 BR-08-131-50 BR-08-144 BR-08-144-50 BR-08-158			
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		PC-300P PC-306P PC-312P PC-400P PC-412P PC-503 PC-512 PC-515 PP-16-039 PP-16-039-50 PP-16-062 PP-16-062-50 PP-16-087 PP-16-087-50 PP-16-105 PP-16-105-50 PP-16-125 PP-16-125-50 PP-16-158 PP-16-158-50 PP-18-197 PP-18-197-50 PP-18-250 PP-18-250-50 PP-18-393 PP-18-393-50 PP-18-591 PP-18-591-50 PP-18-750 PP-18-750-50 PP-22-039-50 PP-22-062-50 PP-22-087-50 PP-22-105-50 PP-22-125-50 PP-22-158-50 PP-22-197-50 PP-24-250-50 PT-28-118-50 PT-28-197-50 BR-06-039 PP-22-039 PP-22-062 PP-22-087 PP-22-105 PP-22-125 PP-22-158 PP-22-197 PP-24-250 PT-28-118 PT-28-197 FLEX008 FLEX009 FLEX025 FLEX026 BR-18-591 BR-18-880 BR-24-070 BR-24-080 BR-24-098 BR-24-197 BR-24-200 BR-24-236 BR-24-276 BR-24-312			
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		BR-24-375 BR-24-393 BR-24-425 BR-24-440 BR-24-443 BR-24-880 PC-606 PP-16-070 PP-16-070-50 PP-22-070 PP-22-070-50 MED100.34 MED100.35 MED100.62 MED100.59.1 45906 45908 45910 45912 45914 96280 96280.0 96280.2 96280.3 96280.4 96280.5 96280.6 96280.7 96280.8 96280.9 96281.3 96281.4 96281.7 MED100.98 26474 26475 26476 26477 26478 26480 26034 26035 26485 09322 09319 09349 09049 09064 09076 09095 09303 09458 09490 09491 09492 BR-4120 26029 26486 26487 26488			
	Key Surgical Specialty Cleaning Brushes	BR-3044 BR-3045 BR-3047 BR-31-118 BR-31-197			

		BR-31-276 BR-3201 BR-3201-50 BR-4140			
	Key Surgical Sterilizer Cleaning Brushes	BR-4000, BR-5000, BR-5200, BR-5400, BR-5450, BR-5455, BR-5500, BR-5600			
	Key Surgical Toothbrush-Style Cleaning Brushes	D-2100BN D-2100BN-50 D-2100SN D-2100SN-50 N-2100 N-2100-50 N-2121 N-2121-50 N-2221-50 N-2000-3 N-3000-3 S-2100 S-2100-50 S-2121-50 S-2131 S-2131-50 S-2300 S-2300-50 UB-2100 UD-2100SN UN-2100 UN-2100-50 UN-2121-50 US-2100 US-2100-50 US-2300 N-3000A N-4000 S-4000 N-3000 N-2000 26023 26032 09084 09459 09320 09478 26491 26492 09485 09460 09325 09488 09489 B-2100 N-2121A N-2121A-50 N-2200 N-2221 S-2121 79325			
	Key Surgical Endoscope Cleaning Brushes	26481 26305 09356 BR-075-18 BR-075-18-50			

		BR-075-24 BR-075-24-50 BR-075-32 BR-075-32-50 BR-075-42 BR-075-42-50 BR-075-99 BR-100-18 BR-100-18-50 BR-100-24 BR-100-24-50 BR-100-32 BR-100-32-50 BR-100-42 BR-100-42-50 BR-100-99, BR-150-18 BR-150-18-50 BR-150-24 BR-150-24-50 BR-150-32 BR-150-32-50 BR-150-42 BR-150-42-50 BR-150-99 BR-200-18 BR-200-18-50 BR-200-24 BR-200-24-50 BR-200-32 BR-200-32-50 BR-200-42 BR-200-42-50 BR-200-99 BR-3030 BR-3030-50 BR-3035 BR-3035-50 BR-3040 BR-3040-50 BR-3202 BR-3202-50 BR-3299 BR-3300 BR-3305 BR-3307 BR-3308 BR-3308-50 BR-3309 BR-3309-50 BR-3310 BR-3310-50 BR-3320 BR-3320-50 BR-3330 BR-3330-50 BR-3340 BR-3340-50 BR-3399 BR-3410 BR-3410-50 BR-3420 BR-3420-50 BR-3701 BR-3702			
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	Key Surgical Endoscope Cleaning Sponge	ES-50	UMDNS: 21- 134 GMDN: 38835		
Irrigation Cannulas Intended Purpose: Intended for use in wound irrigation.	Key Surgical Cannulas (non- sterile)	05001, 05003, 05005, 05007, 05009	UMDNS: 15- 206 GMDN: 62389	084977100000000000000002M5	
Instrument Protectors Intended Purpose: Intended to cover and protect medical instruments.	Key Surgical Instrument Tip Caps	3-48-32, 3-48-44, 3- 06-01, 01800, 3-06-02, I3-06-02, 01801, 3-06- 03, I3-06-03, 01802, 3- 06-04, I3-06-04, 01803, 3-06-05, I3-06- 05, 01804, 3-06-07, I3- 06-07, 01805, 3-11-01, I3-11-01, 1826, 3-11- 02, 01827, 3-11-03, I3- 11-03, 01828, 3-11-04, I3-11-04, 01829, 3-11- 05, 01830, 3-11-06, I3- 11-06, 01831, 3-11-07, 01832, 3-11-08, 01833, 3-11-09, I3-11- 09, 01834, 3-12-01, I3- 12-01, 01838, 3-12-02, I3-12-02, 01839, 3-12- 03, 01840, 3-12-04, 01841, 3-12-05, 01842, 3-12-06, 01843, 3-12-07, I3-12- 07, 01844, 3-12-08, 01845, 3-12-09, I3-12- 09, 01846, 3-13-03, 01835, 3-13-05, 01836, 3-13-07, I3-13- 07, 01837, 3-14-03, 01847, 3-14-05, 01848, 3-14-07, 3-48- 20, 3-07-03, 3-07-05, 3-07-09, 01856, 01857, 01858, 01859, 01860, 3-10-01, 3-10- 02, 3-10-03, 3-10-04, 3- 10-05, 3-01-01S, 3-03- 25, 3-04-97, 3-04-98, 3-04-99, 3-05-02, 3- 05-06, 3-05-07, 3-05- 22, 3-05-23, 3-05-24, 3-05-27, 3-05-28, 3- 05-29, 3-05-30, 3-09- 03, 01814, 3-09-04, I3- 09-04, 01815, 3-09-05, 01816, 3-09-07, 3-09- 08, I3-09-08, 01472,	UMDNS: 16- 222 GMDN: 63247	084977100000000000000003M7	

		01473, 3-09-09, 01474, 01475, 01494, 3-09-10, 3-24-98, 3- 24-99, 3-48-50, 3-80- 03, 3-60-01, 3-60-02, 3-60-03, 3-60-04, 3- 60-05, 3-60-06, 3-60- 07, 3-60-08, 3-60-09, 3-60-10, 3-60-11, 01471, 01476, 01477, 01469, 01470, 01478, 01479, 01492, 01496, 01499, 3-01-01, 01865, 3-01-02, 01890, 3-01-03, 01866, 3-01-04, 01867, 3-01-05, 01891, 3-01-06, 01892, 3-02-01, 01876, 3-02-02, 3-02- 03, 01877, 3-02-04, 01878, 3-02-06, 3-03- 01, 01871, 3-03-02, 01872, 3-03-03, 01873, 3-03-04, 01874, 3-03-05, 01875, 3-03-06, 3-04- 01, 01484, 3-04-02, 01485, 3-04-03, 01486, 3-04-04, 01487, 3-04-05, 01488, 3-04-06, 01489, 3-08-01, 01460, 3-08-02, 01461, 3-08-03, 01462, 3-08-04, 01463, 3-08-05, 01464, 3-08-06, 01465, 3-09-01, 3-09- 02S, 3-15-01, 01868, 3-15-02, 01869, 3-15- 03, 01870, 3-15-04, 01884, 3-15-05, 01885, 3-15-06, 01886, 3-21-03, 3-24- 06, 3-24-20, , 3-42-95, 3-44-01, 3-44-02, 3- 44-03, 3-44-04, 3-44- 05, 3-44-06, 3-44-96, 3-44-97, 3-48-01,, 3- 48-02, 3-48-03, 3-48- 04, 3-48-05, 3-48-06, ,3-48-61, 3-48-62, 3- 48-94, 3-48-95, 3-74- 05, 3-74-06, I3-03-01, I3-03-02, I3-03-03, I3- 04-01, I3-04-02, I3-04- 03, I3-04-04, I3-04-05, I3-04-06, I3-08-01, I3- 08-02, I3-08-03, I3-08- 04, I3-08-05, I3-08- 06,3-03-11, 3-03-12, 3- 03-13, 3-03-15, 3-04- 11, 01806, 3-04-12, 01807, 3-04-13,			
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	Key Surgical Instrument Tip Protectors	PPT001, PPT002, PPT003, PPT004, PPT005, PPT006, PPT007C, CS-1010W, CS-2025W, CS-3050W H-PPT001 H-PPT002 H-PPT003 H-PPT004			

K-Wire and Pin Covers Intended Purpose: Protect and cover K-wires and pins.		H-PPT005 H-PPT006 H-PPT007C H-PPT008C PC006500 PC006600 PC006700 PC006800 PPT002/200 PPT004/200 PPT006/200 PPT008C 01455 01457			
	Key Surgical K-Wire & Steinmann Pin Covers (Non-Sterile)	C-028NS, C-035NS, C-045NS, C-054NS, C-062NS, C-078NS, C-093NS, C-109NS, C-125NS, C-141NS, C-156NS, C-188NS			
Instrument Sterilization Tray Intended Purpose: Protection of devices in cleaning, sterilization and storage.	Key Surgical Plastic Sterilization Trays	PST-0100SB, PST-1100SB, PST-2100SB, PST-3100SB, PST-3200SB, PST-3200SBC-1, PST-3300SB, PST-4200SB	UMDNS:12-143 GMDN:13730		
	Key Surgical Finger Mat	FM-1810			
	Key Surgical Mesh Trays	08132, 08580, 08581, 08761, 08762, 08763, 08772, 08773, 08774, 08776, 08799, 08875, 08896, 08897, 08898, 08899, 08900, 08901, 08902, 08903, 08904, 08905, 08906, 08907, 08908, 08909, 08910, 08911, 08912, 08931, 08935, 08936, 08948, 08950, 08951, 08957, MT-5500, MT-5600, MT-5650, MT-5700, MT-5800, MT-5900, MT-6020, MT-7100, MT-7200, MT-7300, MT-8005, MT-8050, MT-8500, MT-9000, MT-9001, MT-9010, MT-9100, MT-9101, MT-9110, MT-9210, MT-9521, MT-9200 BELBSK116 BELBSK117 BELTRY010 BELTRY013 BSK316 BSK316H BSK317 BSK317H BSK318 BSK318H BSK580X330X75 BSK600X140X50			

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		DIV116 DIV116/4 NIC001R NIC002 NIC003 NIC003DEEP NIC004DEEP NIC004DEEPSJ 08583 08806 08940 08942 08943 08959			
	Key Surgical Scope Baskets	SB-1210 SB-4210 SB-4610 SB-6520			
Tray Corner Protectors Intended Purpose: Protect sterilization tray corners and sterilization wrap	Key Surgical Tray Corner Protectors	42006 42007 42008 42010 42011 50062 50073 H-CC001 H-CC002 PC001600 CC001 CC002 CS-9113 CS-9125C 50063 50064 50075	UMDNS: 15-907 GMDN: 63494 & 65133	084977100000000000000005MB	
Adhesive Remover Intended Purpose: Solution for removing adhesive residue from medical instruments	Adhesive Remover	02111 BC-200-1 BC-200-6	GMDN:64150	084977100000000000000006MD	
Hot Air Film Intended Purpose: Intended for use in Hot Air Sterilization methods	Key Surgical Hot Air Film	36201, 36202, 36203, 36204, 36205, 36206, 36207, 36208, 36209, 36210, 36211	UMDNS: GMDN: 13735	084977100000000000000007MF	
Sterilization Wrap Intended Purpose: Sterile Barrier Wrap	Sterilization Wrap	CB/PRO075 CB/PRO100 CB/PRO1012 CB/PRO1215 CB/PRO1315 CB/SDG/TW1315 CB/TWO060 CB/TWO075	UMDNS: GMDN: 13735	084977100000000000000008MH	

		CB/TWO090 CB/TWO100 CB/TWO120 CB/TWR120 CB/TWRAP060 CB/TWRAP075 CB/TWRAP090 CB/TWRAP100 CB/TWRAP1012 CB/TWRAP120 CB/TWRAP1315 CB/TWRAP1315X CB/TWRAP150 CB/TWRAP150F3W CB/TWRAP18135 CB/TWRAP1815 CB/TWRAP5075 CB/TWRAPDRY050 CB/TWRAPDRY060 CB/TWRAPDRY075 CB/TWRAPDRY090 CB/TWRAPDRY100 CB/TWRAPDRY120 CB/TWRAPDRY1315X CB/TWRAPDRY140 CB/TWY100 CB/TWY120 CB030 CB050 CB060 CB075 CB090 CB100 CB100DB CB1012 CB1014 CB120 CB120DB CB1315 CB1315DB CB140 CB150 CB1540 CB1715 CB1715DB CB1815 CB1815DB CBA/TWRAP120 CBA/TWRAP140 CBA050 CBA075 CBA090 CBA100 CBA120 CBA1415 CBU/TWRAP100 CBU/TWRAP1215 CBU/TWRAP1315 CBU/TWY120 CBU1014 CBU1014DB CBU120 CBU1315 CBU150 CDB/CG060		
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		CDB/CG075 CDB/CG075DB CDB/CG090 CDB/CG100 CDB/CG1012 CDB/CG1012DB CDB/CG1014 CDB/CG120 CDB/CG120DB CDB/CG1215 CDB/CG1215DB CDB/CG1315 CDB/CG1315DB CDB/CG140 CDB/CG150 CDB/CG150DB CDB/CG1815 CDB/CG1815DB CDB/GC120 CDB/GC140 CDB/TWO090 CDB/TWR120 CDB/TWRAP090 CDB/TWRAP100 CDB140 CDB1815 CDB5075 CDG/CB060 CDG/CB075 CDG/CB075DB CDG/CB090 CDG/CB100 CDG/CB1012DB CDG/CB1015 CDG/CB120 CDG/CB120DB CDG/CB1215DB CDG/CB1315 CDG/CB1315DB CDG/CB1815DB CDG/TWO1215 CDG/TWO1315X CDG/TWRAP060 CDG/TWRAP075 CDG/TWRAP090 CDG/TWRAP100 CDG/TWRAP100DB CDG/TWRAP1014 CDG/TWRAP120 CDG/TWRAP120DB CDG/TWRAP1214 CDG/TWRAP1215 CDG/TWRAP1315 CDG/TWRAP150 CDG/TWY1315 CDG075 CDG090 CDG100 CDG120 CDG1215 CDG140 CDG150 CDG1815 CG/CB050 CG/CB060			
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		CG/CB075 CG/CB075DB CG/CB090 CG/CB100 CG/CB100DB CG/CB1012 CG/CB1014 CG/CB1014DB CG/CB1075 CG/CB1075DB CG/CB1090 CG/CB120 CG/CB1215 CG/CB1215X CG/CB1315 CG/CB1315/P120 CG/CB1315DB CG/CB1315X CG/CB140 CG/CB140X CG/CB150 CG/CB1715 CG/CB1715/F4 CG/CB1815 CG/CB1815/P72 CG/CB5045 CG/CBA120 CG/CBU075 CG/CBU090 CG/CBU100 CG/CBU100DB CG/CBU1012 CG/CBU1014 CG/CBU1090 CG/CBU1215 CG/CBU1315DB CG/CBU1315X CG/PRO1215 CG/PRO1815 CG/TWO060 CG/TWO090 CG/TWO1012 CG/TWO1012DB CG/TWO1014 CG/TWO1014DB CG/TWO1075 CG/TWO1075DB CG/TWO1090DB CG/TWO120 CG/TWO1215 CG/TWO1215DB CG/TWO1215PZDB CG/TWO1315 CG/TWO140 CG/TWO1715 CG/TWO1715DB CG/TWO1815 CG/TWO1815DB CG/TWR060 CG/TWR090DB CG/TWR100 CG/TWR100DB CG/TWR1014 CG/TWR1090DB CG/TWR1215PZDB		
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		CG/TWR1315 CG/TWR1315PZDB CG/TWR1715DB CG/TWR1815PZDB CG/TWRAP060 CG/TWRAP075 CG/TWRAP075DB CG/TWRAP090 CG/TWRAP090DB CG/TWRAP100 CG/TWRAP100DB CG/TWRAP1012 CG/TWRAP1012DB CG/TWRAP1014 CG/TWRAP1014DB CG/TWRAP1075 CG/TWRAP1090 CG/TWRAP1090DB CG/TWRAP120 CG/TWRAP120DB CG/TWRAP1215 CG/TWRAP1215DB CG/TWRAP1215PZDB CG/TWRAP1315 CG/TWRAP1315DB CG/TWRAP1315PZ CG/TWRAP1315PZDB CG/TWRAP140 CG/TWRAP140DB CG/TWRAP150 CG/TWRAP1715DB CG/TWRAP1815 CG/TWRAP1815/F4 CG/TWRAP1815DB CG/TWRAP5075 CG/TWRAP5075DB CG/TWRAPDRY060DB CG/TWRAPDRY075 CG/TWRAPDRY090 CG/TWRAPDRY090DB CG/TWRAPDRY100 CG/TWRAPDRY1012 CG/TWRAPDRY1014 CG/TWRAPDRY1075 CG/TWRAPDRY1090 CG/TWRAPDRY120 CG/TWRAPDRY120DB CG/TWRAPDRY1215 CG/TWRAPDRY1315 CG/TWRAPDRY1315D CG/TWRAPDRY1315X CG/TWRAPDRY140 CG/TWRAPDRY150 CG/TWRAPDRY1715 CG/TWRAPDRY1815 CG/TWRAPDRY1815M CG/TWY060 CG/TWY075DB CG/TWY090 CG/TWY090DB CG/TWY100 CG/TWY100DB CG/TWY1012 CG/TWY1012DB CG/TWY1090		
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		CG/TWY1090DB CG/TWY1215 CG/TWY1215PZDB CG/TWY1315 CG/TWY1315DB CG/TWY1815 CG/WB120 CG/WB1315 CG/WB1815 CG060 CG075 CG075DB CG090 CG090/P150 CG100 CG100/P150 CG100DB CG120 CG120DB CG1215 CG1315 CG140 CG150 CG1715DB CG1815DB CG5075 CGP/CB100 CGP/CB120 CGP/CB1715 CGP/CB1815 CGP/CBU100 CGP/CBU1014 CGP/CBU1014DB CGP/CBU1090 CGP/CBU1215 CGP/CBU1315 CGP/CBU140 CGP/CBU1815 CGP/TWO100 CGP/TWO1012 CGP/TWO1215 CGP/TWO1815 CGP/TWRAP060 CGP/TWRAP060DB CGP/TWRAP075 CGP/TWRAP075DB CGP/TWRAP090 CGP/TWRAP100 CGP/TWRAP1012 CGP/TWRAP1075 CGP/TWRAP120 CGP/TWRAP1215 CGP/TWRAP1315 CGP/TWRAP150 CGP/TWRAP1815 CGP/TWY075 CGP/TWY100 CGP/TWY1315 CGP/TWY1815 CGP1315 CGP150 CGX/CB075 CGX/CB075DB CGX/CB090 CGX/CB100		
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		CGX/CB100DB CGX/CB1012 CGX/CB1012DB CGX/CB1014 CGX/CB1090 CGX/CB1090DB CGX/CB1215 CGX/CB1215DB CGX/CB1315 CGX/CB1315/P120 CGX/CB1315P120DB CGX/CB1715 CGX/CB1715DB CGX/CB1815 CGX/CB1815DB CGX/CB5075 CGX/CB5075DB CGX/CBU060 CGX/CBU060DB CGX/CBU100 CGX/CBU1012 CGX/CBU1014 CGX/CBU1014DB CGX/CBU1090 CGX/CBU1090DB CGX/CBU1215 CGX/CBU1315 CGX/CBU1315DB CGX/CBU1815 CGX/TWO1012DB CGX/TWO1090DB CGX/TWO1215PZDB CGX/TWO1315 CGX/TWR1090DB CGX/TWR1215PZDB CGX/TWR1715DB CGX/TWRAP075DB CGX/TWRAP090 CGX/TWRAP090DB CGX/TWRAP100 CGX/TWRAP100DB CGX/TWRAP1012 CGX/TWRAP1012DB CGX/TWRAP1090DB CGX/TWRAP1215 CGX/TWRAP1215PZDB CGX/TWRAP1315 CGX/TWRAP1315PZDB CGX/TWRAP1715DB CGX/TWRAP1815 CGX/TWRAP1815DB CGX/TWRAP5075 CGX/TWRAP5075DB CGX/TWRAPD100DB CGX/TWRAPD1215DB CGX/TWRAPD1315DB CGX/TWRAPDRY100 CGX/TWRAPDRY1215 CGX/TWRAPDRY1315 CGX/TWY090DB CGX/TWY1012DB CGX/TWY1090DB CGX/TWY1215PZDB CGX/TWY1315 CGX/TWY1315DB		
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		CGX090 CGX100 CGX100DB CGX120 CGX1715DB REL340G/CBU100 REL340G/CBU1014 REL340G/CBU1215 REL340G/CBU1315 RELGRN/CB100 RELGRN/CB1050 RELGRN/CB1315 RELGRN/CB140 RELGRN/WB1815 WB/TDRY100DB WB/TWO075 WB/TWO1012 WB/TWO1014 WB/TWO1014DB WB/TWO1315 WB/TWRAP060 WB/TWRAP075 WB/TWRAP090 WB/TWRAP100 WB/TWRAP100DB WB/TWRAP1012 WB/TWRAP1014DB WB/TWRAP1075 WB/TWRAP1215 WB/TWRAP1215DB WB/TWRAP1315 WB/TWRAP1815 WB/TWRAPDRY060 WB/TWRAPDRY090 WB/TWRAPDRY100 WB/TWRAPDRY120 WB/TWRAPDRY1315X WB/TWRAPDRY150 WB/TWRAPDRY150F3 WB/TWY090 WB/TWY1014 WB/TWY1215 WB075 WB090 WB100 WB1014 WB120 WB140 CBA060 CBU140 CDG1315 CG/TWRAPDRY060 CGX/TWY1215 WB/TWRAPDRY1012 MC-CBA/TWRAP090 MC-CBA/TWRAP100 MC-CBA/TWRAP120 RELGRN/CBU100 RELGRN/CBU140 CG/CBU120 CGX/TWY090 CGX/TWY1012 CG/CBU1815 CB/TDRY075 CB/TDRY090		
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		CB/TDRY100 CB/TDRY060 CB/TDRY120 CGX/TWR1815			
Transportation Wrap Intended Purpose: Transportation Barrier Wrap	Transportation wrap and covers	PC000100 PC000200 PC000300 PC000500 PC000600 PC00900 PRO060 PRO090 TDRY075 TDRY090 TDRY100 TDRY120 TDRY3024 TDRYPACK1012 TDRYPACK1815 TWO050 TWO060 TWO075 TWO075DB TWO090 TWO100 TWO1012 TWO1012DB TWO1014 TWO120 TWO1215 TWO1215DB TWO1315 TWO140 TWO140DB TWO150 TWO150DB TWO1715DB TWO1815 TWO5075 TWR060 TWR075 TWR075DB TWR090 TWR100 TWR100DB TWR1012DB TWR1014 TWR1090DB TWR120 TWR1215DB TWR1315 TWR140 TWR150 TWR1715DB TWR1815 TWR5075DB TWRAP050 TWRAP060 TWRAP075 TWRAP075DB TWRAP090 TWRAP100 TWRAP100DB TWRAP1012 TWRAP1012DB	GMDN: 13735	0849771000000000000009MK	

		TWRAP1014 TWRAP1090DB TWRAP120 TWRAP1215 TWRAP1215DB TWRAP1315 TWRAP1315DB TWRAP140 TWRAP140DB TWRAP150 TWRAP150DB TWRAP1715 TWRAP1715DB TWRAP1815 TWRAP1815DB TWRAP5090 TWRAP5390 TWRAP7537 TWRAP75375 TWRAPDRY050 TWRAPDRY060 TWRAPDRY075 TWRAPDRY090 TWRAPDRY100 TWRAPDRY1012 TWRAPDRY1014 TWRAPDRY120 TWRAPDRY1315 TWRAPDRY140 TWRAPDRY1815 TWRAPDRY3015 TWRAPDRY3015SGL TWRAPDRY5075 TWRAPDRY7560 TWRAPDRYOFFCUT TWY075 TWY075DB TWY090 TWY100 TWY100DB TWY1012 TWY1014 TWY120 TWY1215 TWY1215DB TWY1315 TWY1315DB TWY140 TWY1715 TWY1715DB TWY1815 CDBAG002G H-THCOVER001 H-THCOVER002 H-THCOVER003 H-THOCOVER001 H-THOCOVER002 H-THOCOVER003 H-THRCOVER001 H-THRCOVER002 H-THRCOVER003 H-THYCOVER001 H-THYCOVER002 H-THYCOVER003 PC000700		
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		PC000800 PC000900 PC011500 PC011600 TCOVER001 TCOVER002 TCOVER003 TCOVER007 TCOVER008 TCOVERDRY001 TCOVERDRY002 TCOVERDRY003 TCOVER-RED001 TCOVER-RED002 TCOVER-RED003 TCOVER-YELL001 TCOVER-YELL002 TCOVER-YELL003			
Transportation Wrap Intended Purpose: Transportation Barrier Wrap	Transportation Wrap Mats	DRYMAT001 DRYMAT002 DRYMAT003 DRYMAT003P500 DRYMAT004 DRYMAT005 DRYMAT006 DRYMAT007 DRYMAT008 DRYMAT009 DRYMAT010 DRYMAT011 DRYMAT013 DRYMAT018 DRYMATGRN001 DRYMATGRN002 DRYMATGRN003 H-DRYMAT001 H-DRYMAT002 H-DRYMAT003 H-DRYMAT004 H-DRYMAT011 H-DRYMAT018 H-DRYMATGRN001 H-DRYMATGRN002 H-DRYMATGRN003 H-MAT001 H-MAT002 H-MAT003 MAT001 MAT002 MAT003 MAT004 MAT005 MAT007 PC002300 PC002400	GMDN: 13735		
Container Filters Intended Purpose: For use with sterilization containers.	Container Filters	01140 01141 01142 01143 01144 01145 01148 01149 01152 01153	GMDN: 60909	08497710000000000000000010M4	

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		01167			
		01168			
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		1070020			
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		ME01194			
		ME26515			

		ME27325 ME27335 ME27345 ME27355 ME27365 01149MED 01181MED 01186MED 01141MED 01183MED 01305			
Tray Liners Intended Purpose: For use in sterilization of medical devices.	Tray Liners	49937 49938 50110 51448 1136011 1137011 CBL003 CBL300X300H CBL350X350 CBL400X400 CBL400X600 CBL500X700 CBL580X350 H-CBL001 H-CBL002 H-CBL003 H-TLC004 H-TLC005 H-TLC006 H-TLC007 H-TLC008 H-TLC009 H-TLC010 H-TLC011 H-TLC012 H-TLC013 H-TLC078 H-TLC109 H-TLC110 H-TLC111 H-TLC119 H-TLC213 H-TLC214 H-TLC215 LIB1328 LIB250X320 LIB300X360 LIB300X500 LIB3025 LIB3050 LIB400X500 LINH3020 LINH3041 LINH4555 MILB002 MILB003 MILB004 MILB005 MILB006 MILB007 MILB008 MILB009 MILB011 MILB012	GMDN:60908	08497710000000000000011M6	

		MILB016			
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		MILB022			
		MILB025			
		MILB027			
		MILB029			
		MILB056			
		MILB120X250			
		MILB130X230			
		MILB170X270			
		MILB250X300			
		MILB300X400			
		MILB305X450			
		MILB350x450			
		MILB375X600			
		MILB450X650			
		MILB500X900			
		PC002100			
		PC002200			
		PC008800			
		PC008900			
		PC009000			
		PC009100			
		PC009200			
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		TLC024 TLC027 TLC029R TLC030 TLC031 TLC034 TLC036 TLC045 TLC051 TLC052 TLC055 TLC060 TLC066 TLC069 TLC071 TLC072 TLC078 TLC079 TLC081 TLC085 TLC086 TLC087 TLC095 TLC096 TLC098 TLC100 TLC102 TLC103 TLC104 TLC107 TLC108 TLC109 TLC110 TLC114 TLC115 TLC116 TLC120 TLC122 TLC220 TLC3044 TLC340 TLC3535 TLC3548 TLC420X330 TLC450 TLC5060 TLC520X360 TLC540X250 TLP-012-018 TLP-020-025 TLC050 TLC058 1136011 1137011			
	Soaker Sheets	H-SOK001SS H-SOK002SS H-SOK003SS H-SOK006SS H-SOK008SS H-SOK009SS H-SOK010SS H-SOK014SS PC002000 PC012200 PC012300	GMDN:61664		

		PC013100 PC013200 SOK001SS SOK002SS SOK003SS SOK004SS SOK005SS SOK006SS SOK007SS SOK008SS SOK009SS SOK010SS SOK011SS SOK012SS SOK013SS SOK016SS SOK200X350 SOK3030 SOK3045 SOK305X545 SOK3060 SOK350X350 SOK350X640 SOK375X300 SOK550X380 SOK560X1000 SOK560X1230 SOK560X1300 SOK560X1400 SOK560X280 SOK590X1200 SOK640X640 SOK001SS			
Maintenance Oil Intended Purpose: Intended for use in lubricating medical devices.	Lubrinol / Enginol	02004 02006 02005	GMDN: 15772	084977100000000000000012M8	
Chirol Ultra Intended Purpose: Cleaning solution for removing soils from metallic surfaces.	Chirol Ultra	02110	GMDN: 63385	084977100000000000000013MA	

We hereby appoint

Medical Device Safety Service (MDSS)
Schiffgraben 41
D-30175 Hannover
Germany

as the European Authorized Representative as defined in Article 2(32) of the MDR.

Conformity Assessment Route: Annex IV

Issued By:

Signature:



Date: 2021-12-28

Name: Coletta Cohara
Position: Director Quality and Regulatory Compliance
Place of Issue of Key Surgical LLC
DoC: 8101 Wallace Rd.
Eden Prairie, MN 55344
USA