smiths medical bringing technology to life	**Declaration of Conformity** S1066: Invasive Patient Pressure Monitoring Devices and Accessories	DoC-255 Revision Number: 103

Legal Manufacturer:	Smiths Medical ASD Inc. 6000 Nathan Lane North Minneapolis, Minnesota 55442 USA
EU Representative:	Smiths Medical Czech Republic a. s. Olomoucká 306, Hranice 1 - Město, 753 01 Hranice, Czech Republic
Product Tradename(s):	Medex™, LogiCal®
Conformity Assessment Route:	Annex VII
Notified Body:	N/A
EC Certificate Number:	N/A

Smiths Medical ASD, Inc. hereby declares under its sole responsibility that the product(s) referenced conform to the relevant provisions of the European Union Council Directive 93/42/EEC on Medical Devices (the MDD) as amended by Directive 2007/47/EC.

Authorized Signatory:

Signature: Stacy Novak Date: 25 Sep 2019

Name: Stacy Novak

Title: Director, Regulatory Operations

Location of Signatory: Minneapolis, MN, USA

Appendix 1: Product List

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
1.	MX260	MX260CZ	Clamp-DPS for 1 Transducer	Smiths Medical Czech Republic a.s. Olomoucká 306,753 01 Hranice, Czech Republic	35504	I ns/nm	1
2.	MX260-PM	MX260-PMCZ	LogiCal Patient Mount	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	35504	I ns/nm	1
3.	MX261P1	MX261P1CZ	Clamp-DPS for Bracket	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	35504	I ns/nm	1
4.	MX262P1	MX262P1CZ	Bracket-DPS for 2 Transducers	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	35504	I ns/nm	1
5.	MX263P1	MX263P1CZ	Bracket-DPS for 3 Transducers	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	35504	I ns/nm	1
6.	MX264	MX264CZ	Bracket-DPS for 4 Transducers	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	35504	I ns/nm	1
7.	MX267C2	MX267C2CZ	LogiCal Bracket	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	35504	I ns/nm	1
8.	MX1821-B	MX1821-BCZ	C-Fusor Squeeze Bulb	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	42398	I ns/nm	1

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
9.	MX1821-G	MX1821-GCZ	C-Fusor Pressure Gauge	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	13100	I ns/nm	1
10.	MX240P1	MX240P1CZ	Manifold Horizontal	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	61952	I ns/nm	1
11.	MX244P1	MX244P1CZ	Clamp For 1/2" Pole	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	61952	I ns/nm	1
12.	MX4705P1	MX4705P1CZ	Cuff Clear 500ML	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	13100	I ns/nm	1
13.	MX4710P1	MX4710P1CZ	Cuff Clear 1000ML	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	13100	I ns/nm	1
14.	MX4805P1	MX4805P1CZ	Pressure Infusor C Fusor 500ML Bag	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	13100	I ns/nm	1
15.	MX4806	MX4806CZ	C-Fusor Replacement Bag 500ML	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	13100	I ns/nm	1
16.	MX4810P1	MX4810P1CZ	Pressure Infusor C Fusor 1000ML Bag	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	13100	I ns/nm	1
17.	MX4830P1	MX4830P1CZ	Extension on MX4810	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	13100	I ns/nm	1

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
18.	MX800P1	MX800P1CZ	Modular Transducer Plate	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	35504	I ns/nm	1
19.	MX800-S	MX800-SCZ	Novastrap	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	35709	I ns/nm	1
20.	MX257C2	MX257C2CZ	Transtar Bracket	Smiths Medical Czech Republic a.s. Olomoucká 306, 753 01 Hranice, Czech Republic	35504	I ns/nm	1
21.	MX961Y08	MX961Y08	Single Line for Siemens 4th Generation	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
22.	MX962Z02P1	MX962Z02P1	Two Gang for Hp 12 Pin Merlin	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
23.	MX962Z42P1	MX962Z42P1CZ	Two Gang for Spacelabs, Protocal, Critikon	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
24.	MX962Z50P1	MX962Z50P1CZ	2 Gang w/o Plug	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
25.	MX962Z02ST	MX962Z02STCZ	Two Gang for Hp 12 Pin Merlin	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
26.	MX962Z03P1	MX962Z03P1CZ	Two Gang for Physio Control	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
27.	MX962Z04P1	MX962Z04P1CZ	Two Gang for Datascope/Kontron	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
28.	MX962Z14P1	MX962Z14P1CZ	Cable Two Gang for Mennen	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
29.	MX962Z15P1	MX962Z15P1CZ	Two Gang for Marquette M 7000	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
30.	MX962Z17P1	MX962Z17P1CZ	Two Gang for S & W. Narco/Airshields	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
31.	MX962Z20P1	MX962Z20P1CZ	Two Gang for Datex	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
32.	MX962Z22P1	MX962Z22P1CZ	Two Gang for Nihon Kohde N	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
33.	MX962Z62P1	MX962Z62P1CZ	Two Gang for Datex	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
34.	MX962Z64P1	MX962Z64P1CZ	Fukuda Denshi	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
35.	MX962Z68P1	MX962Z68P1CZ	Two Gang for Marquette T Ram	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
36.	MX962Z70P1	MX962Z70P1CZ	Two Gang for PPG Midas	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
37.	MX962Z74P1	MX962Z74P1CZ	Two Gang for Bard	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
38.	MX963Y08	MX963Y08CZ	Three Gang for Siemens 4th Generation	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
39.	MX963Y132	MX963Y132CZ	Triple Logical Cable for Witt Biomedical	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
40.	MX963Z04P1	MX963Z04P1CZ	Three Gang for Datascope /Kontron	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
41.	MX963Z15P1	MX963Z15P1CZ	Three Gang for Marquette M7000	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
42.	MX963Z20P1	MX963Z20P1CZ	Three Gang for Datex	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
43.	MX963Z22P1	MX963Z22P1CZ	Three Gang for Nihon Kohden	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
44.	MX963Z42P1	MX963Z42P1CZ	Three Gang for Spacelabs, Protocal, Critik	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
45.	MX963Z50P1	MX963Z50P1CZ	Three Gang w/o Plug	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
46.	MX963Z68P1	MX963Z68P1CZ	Logical 3 Channel Cable Marquette Tram	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
47.	MX964Y08	MX964Y08CZ	Four Gang for Siemens 4th Generation	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
48.	MX964Z02P1	MX964Z02P1CZ	Four Gang for Hp 12 Pin Merlin	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
49.	MX964Z20P1	MX964Z20P1CZ	Four Gang for Datex	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
50.	MX964Z22P1	MX964Z22P1CZ	Four Gang for Nihon Kohden	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
51.	MX964Z50P1	MX964Z50P1CZ	Four Gang w/o Plug (10"/10"+15")	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
52.	MX964Z85	MX964Z85CZ	Four Gang Cable for Medos Hlm Deltastream	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
53.	MX980-02	MX980-02CZ	Cable Hp 12 Pin	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
54.	MX980-04	MX980-04CZ	Transtar Cable for Datascope/Kontron	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
55.	MX980-14	MX980-14CZ	Transtar Cable for Mennen	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
56.	MX980-17	MX980-17CZ	Transtar Cable for S&W Narco/Airshields	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
57.	MX980-20	MX980-20CZ	Transtar Cable for Datex	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
58.	MX980-42	MX980-42CZ	Cable for Space Lab	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
59.	MX980-50	MX980-50CZ	Cable Universal	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
60.	MX980-62	MX980-62CZ	Transtar Cable for Datex	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
61.	MX981-105	MX981-105CZ	Transtar Cable for Schwarzer Cardis 5000	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
62.	MX981-132	MX981-132CZ	Cable: Transtar Witt Monitor Series	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
63.	MX981-15	MX981-15CZ	Cable for Marquette	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
64.	MX981-19	MX981-19CZ	Cable: Handwired	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
65.	MX981-22	MX981-22CZ	Cable: Handwired	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
66.	MX981-37	MX981-37CZ	Cable:P.P.G.RM300	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
67.	MX981-44	MX981-44CZ	Cable for Kontron Kaat	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
68.	MX981-47	MX981-47CZ	Cable for Quinton Q Cath 5 Pin Male	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
69.	MX981-64	MX981-64CZ	Cable for Fukuda	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
70.	MX981-68	MX981-68CZ	Cable for Marquette Tram	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
71.	MX981-69	MX981-69CZ	Transtar Interface Cable for Sarns Monitor	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
72.	MX900-02	MX900-02CZ	Cable for H-P 12 Pin	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
73.	MX900-04	MX900-04CZ	Cable for Datascope & Kontron	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
74.	MX901-08	MX901-08CZ	Cable for Siemens 4th Generation	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
75.	MX901-19	MX901-19CZ	Cable for Siemens SI	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
76.	MX901-68	MX901-68CZ	Cable for Marquette Tran 200	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
77.	MX901-74	MX901-74CZ	Novatrans Cable for Bard	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
78.	MX901-105	MX901-105CZ	Novatrans Cable for Schwarzer Cardis 5000	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
79.	MX901-132	MX901-132CZ	Cable: Novatrans Witt Monitor Series 4 Front	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
80.	MX961Y05	MX961Y05CZ	Single Line for Honeywell (E for M)	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
81.	MX961Y08L1	MX961Y08L1CZ	Single Line for Siemens SC 9000	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
82.	MX961Y08L2	MX961Y08L2CZ	Single Line for Siemens SC9000	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
83.	MX961Y08L20	MX961Y08L20CZ	Single Line for Siemens 6 Metres	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
84.	MX961Y118	MX961Y118CZ	Cable: Single Line for Dantec	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
85.	MX961Y126	MX961Y126CZ	LogiCal Cable for Scholar Vital Signs Mon	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
86.	MX961Y130	MX961Y130CZ	LogiCal Cable for Biotronik EP Control	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
87.	MX961Y132	MX961Y132CZ	Single LogiCal Cable for Witt Biomedical	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
88.	MX961Y19	MX961Y19CZ	Single Line for Siemens Mingograph	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
89.	MX961Y19L20	MX961Y19L20CZ	Single Line for Siemens Mingograph (20FT)	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
90.	MX961Y44	MX961Y44CZ	Single Line for Kontron Kaat	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
91.	MX961Y68L20	MX961Y68L20CZ	Single Line for Marquette Tram (20FT)	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
92.	MX961Y79	MX961Y79CZ	Single Line for Jostra Hlm	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
93.	MX961Y80	MX961Y80CZ	Cable Single Line for Prucka Cardiolab EP	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
94.	MX961Z01P1	MX961Z01P1CZ	Cable Logical Hewlet Packard Twinax	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
95.	MX961Z03P1	MX961Z03P1CZ	Single Line for Physio Control	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
96.	MX961Z04P1	MX961Z04P1CZ	Single Line for Datascope/Kontron	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
97.	MX961Z14P1	MX961Z14P1CZ	Single Line for Mennen	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
98.	MX961Z13P1	MX961Z13P1CZ	Single Line for Hellige (Servomed)	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
99.	MX961Z15P1	MX961Z15P1CZ	Single Line for Marquette M7000	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
100.	MX961Z17P1	MX961Z17P1CZ	Single Line for S & W. Narco/Airshields	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
101.	MX961Z19P1	MX961Z19P1CZ	Single Line for Siemens Mingograph	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
102.	MX961Z22P1	MX961Z22P1CZ	Single Line for Nihon Kohden	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
103.	MX961Z25P1	MX961Z25P1CZ	Single Logical Cable Corometrics	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
104.	MX961Z34P1	MX961Z34P1CZ	Cable for HP Fetal Monitor	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
105.	MX961Z42P1	MX961Z42P1CZ	Single Line for Spacelabs, Protocal, Criti	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
106.	MX961Z44P1	MX961Z44P1CZ	Single Line for Kontron Kaat	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
107.	MX961Z47P1	MX961Z47P1CZ	Single Line for Quinton Q-Cath.	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
108.	MX961Z50P1	MX961Z50P1CZ	Single Line w/o Plug (12 ')	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
109.	MX961Z62P1	MX961Z62P1CZ	Single Line for Datex	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
110.	MX961Z64P1	MX961Z64P1CZ	Fukuda Denshi	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
111.	MX961Z68P1	MX961Z68P1CZ	Single Line for Marquette Tram	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
112.	MX961Z74P1	MX961Z74P1	Single Line for Bard	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
113.	MX961Z86	MX961Z86CZ	LogiCal Cable for Cardiotek EP Tracer	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
114.	MX962Y100	MX962Y100CZ	Logical Double Line for Bruker	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
115.	MX962Y118	MX962Y118CZ	Cable: Double Line for Dantec	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
116.	MX962Y126	MX962Y126CZ	Cable for Scholar	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
117.	MX962Y132	MX962Y132CZ	Double Logical Cable for Witt Biomedical	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
118.	MX962Y19	MX962Y19CZ	Two Gang for Siemens Mingograph	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
119.	MX981-100	MX981-100	Kabel Transtar F.Bruker	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
120.	MX961Y68ST	MX961Y68STCZ	Single Line for Marquette Tram	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
121.	MX961Z02ST	MX961Z02STCZ	Single Line for HP 12 PI N Merlin	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1
122.	MX962Y08ST	MX962Y08STCZ	Two Gang for Siemens 4th Generation	Semicol Medical D.O.O. Trubarjeva 5 Sentjernej, Slovenia SLO-8310	47487	I ns/nm	1

Appendix 2: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
100	Initial release of DoC for the purpose of capturing class Ins/nm self-certified products whose Legal Manufacture is Hranice, within the product scope referenced. SKU's MX260CZ, MX260-PMCZ, MX261P1CZ ,MX262P1CZ, MX263P1CZ, MX264CZ, MX267C2CZ, MX1821-BCZ, MX1821-GCZ, MX240P1CZ, MX244P1CZ, MX4705P1CZ, MX4710P1CZ, MX4805P1CZ, MX4806CZ, MX4810P1CZ, MX4830P1CZ, MX800P1CZ, MX800-SCZ removed from DoC-239. SKU's MX961Y08, MX962Z02P1, MX962Z42P1, MX962Z50P1CZ, MX962Z62P1, MX981-100 removed from DoC-089.	Dominique Neisz	03-JUL-2018
101	The purpose of this revision is to include the following SKU's which were identified as saleable class Ins/nm IBPM hardware as well as to correct GMDN terms. MX962Z02STCZ, MX962Z03P1CZ, MX962Z04P1CZ, MX962Z14P1CZ, MX962Z15P1CZ, MX962Z17P1CZ, MX962Z20P1CZ, MX962Z22P1CZ, MX962Z62P1CZ, MX962Z64P1CZ, MX962Z68P1CZ, MX962Z70P1CZ, MX962Z74P1CZ, MX963Y08CZ, MX963Y132CZ, MX963Z04P1CZ, MX963Z15P1CZ, MX963Z20P1CZ, MX963Z22P1CZ, MX963Z42P1CZ, MX963Z50P1CZ, MX963Z68P1CZ, MX964Y08CZ, MX964Z02P1CZ, MX964Z20P1CZ, MX964Z22P1CZ, MX964Z50P1CZ, MX964Z85CZ, MX980-02CZ, MX980-04CZ, MX980-14CZ, MX980-17CZ, MX980-20CZ, MX980-42CZ, MX980-50CZ, MX980-62CZ, MX981-105CZ, MX981-132CZ, MX981-15CZ, MX981-19CZ, MX981-22CZ, MX981-37CZ, MX981-44CZ, MX981-47CZ, MX981-64CZ, MX981-68CZ, MX981-69CZ, MX900-02CZ, MX900-04CZ, MX901-08CZ, MX901-19CZ, MX901-68CZ, MX901-74CZ, MX901-105CZ, MX901-132CZ, MX961Y05CZ, MX961Y08L1CZ, MX961Y08L2CZ, MX961Y08L20CZ, MX961Y118CZ, MX961Y126CZ, MX961Y130CZ, MX961Y132CZ, MX961Y19CZ,	Dominique Neisz	30-JUL-2018

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
	MX961Y19L20CZ, MX961Y44CZ, MX961Y68L20CZ, MX961Y79CZ, MX961Y80CZ, MX961Z01P1CZ, MX961Z03P1CZ, MX961Z04P1CZ, MX961Z14P1CZ, MX961Z13P1CZ, MX961Z15P1CZ, MX961Z17P1CZ, MX961Z19P1CZ, MX961Z22P1CZ, MX961Z25P1CZ, MX961Z34P1CZ, MX961Z42P1CZ, MX961Z44P1CZ, MX961Z47P1CZ, MX961Z50P1CZ, MX961Z62P1CZ, MX961Z64P1CZ, MX961Z68P1CZ, MX961Z74P1, MX961Z86CZ, MX962Y100CZ, MX962Y118CZ, MX962Y126CZ, MX962Y132CZ, MX962Y19CZ		
102	Updated to latest template revision (from 003 to 105). Removed S1105 from the header as it isn't a valid STED. S1066 is the applicable STED. Added "Invasive Patient Pressure Monitoring Devices and Accessories" as the STED title to align with the STED's title in Agile. Changed the legal manufacturer from MCZH to MMSP as per FM-DVSOP8005-05. Added Hranice, Czech Republic as EU Representative. An EU Representative is needed if a product is commercially distributed in the EU and not manufactured in the EU. Since the Legal Manufacturer is changing to MMSP, an EU Representative is needed. Added "Medex™ and LogiCal®" as Product Tradenames as they reflect the tradenames of the affected SKUs. Split the "Catalog Number" column into two -- "External Reference Number" and "Internal Reference Number" to account for the CZ/non-CZ SKUs. Moved MX257C2CZ from DoC-239 as DoC-239 and DoC-255 both related to the same STED and house Class Ins/nm SKUs. DoC-239 is being obsoleted as it has duplicate SKUs to DoC-255. The only SKU listed on DoC-239 that’s not on DoC-255 is MX257C2CZ. Since it's Class Ins/nm and relates to the same STED, the SKU was added to DoC-255.	Alicia Wilson	03-SEP-2019

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
	Changed the GMDN Code for MX1821-GCZ and MX4830P1CZ from 35529 to 13100 to better align with the SKUs' descriptions. Changed the GMDN Code for MX4705P1CZ, MX4710P1, MX4805P1CZ, MX4806CZ, MX4810P1CZ from 34978 to 13100 to better align with the SKUs' descriptions. Changed the GMDN Code for MX1821-BCZ from 35529 to 42398 to better align with the SKU's description.		
103	Added MX961Y68STCZ, MX961Z02STCZ and MX962Y08STCZ from DoC-069 as they're Class Ins/nm. Removed the duplicate MX962Z62P1CZ as it only needs to be listed once. Changed the GMDN Code for MX257C2CZ from 61952 to 35504 to better align with the SKUs' descriptions. Changed the GMDN Code for MX240P1CZ from 35504 to 61952 to better align with the SKUs' descriptions. Changed the GMDN Code for MX260-PMCZ, MX267C2CZ, MX261P1CZ and MX260CZ from 41893 to 35504 to better align with the SKUs' descriptions. Changed the GMDN Code for MX244P1CZ from 41893 to 61952 to better align with the SKUs' descriptions. Changed the GMDN Code for MX961Y68STCZ, MX961Z02STCZ and MX962Y08STCZ from 14119 to 47487 to better align with the SKUs' descriptions.	Alicia Wilson	24-SEP-2019