smiths medical bringing technology to life	**Declaration of Conformity** S1066: Invasive Patient Pressure Monitoring Devices and Accessories	DoC-069 Revision Number: 127

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™, NovaTrans® Pressure Transducers, TranStar® Pressure Transducers, LogiCal® pressure transducers
Conformity Assessment Route:	Annex II (excluding Section 4)
Notified Body:	BSI Healthcare Medical Device Certification Notified Body #2797
EC Certificate Number:	CE 669121

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: 22OCT2019

Name: Stacy Novak

Title: Director, Regulatory Operations

Location of Signatory: Minneapolis, MN, United States

Appendix 1: Product List

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
1.	DPS562296	DPS562296CZ	Geschlossenes Druckmess- Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
2.	DPS564134	DPS564134CZ	Art Set Mit ZVD	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
3.	DPS564212	DPS564212CZ	LogiCal Version CR460118	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
4.	DPS564833	DPS564833CZ	Druckmessset Einfach MIT ZVD	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
5.	DPS564928	DPS564928CZ	1 Fach Druckmess Lukas KRH Neuss	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
6.	DPS565837	DPS565837CZ	Druckmess-Set ART/ZVD	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
7.	DPS565873	DPS565873CZ	ART./VEN. Druckmess-Set AKK ESSEN	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
8.	DPS566307	DPS566307CZ	Druckmess-Set Arteriell	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
9.	DPS566329	DPS566329CZ	Einfach-Set MIT ZVD Klinikum Region Hannover	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
10.	DPS566339	DPS566339CZ	DPS-Charite Basis Rot	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
11.	DPS566387	DPS566387CZ	AS-Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
12.	DPS566388	DPS566388CZ	AS-Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
13.	DPS566391	DPS566391CZ	Anti-Shunt-Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
14.	DPS567007	DPS567007CZ	Antishuntsystem 180cm Stade	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
15.	MX9624AS	MX9624ASCZ	DPS Pressure Monitoring Kit W/ Anti Shunt	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
16.	MX9624ASV	MX9624ASVCZ	DPS Pressure Monitoring Kit W/ Anti Shunt	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
17.	MX9624ASVLT	MX9624ASVLTCZ	DPS Pressure Monitoring Kit W/ Anti Shunt	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
18.	MX9624ASVLT-MAV	MX9624ASVLT-MAVCZ	Single Line Anti-Shunt Min-Residual Luer Stopcock	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
19.	MX9625AS	MX9625ASCZ	DPS Pressure Monitoring Kit w/ Anti Shunt	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
20.	DPS550143	DPS550143CZ	Cath Labl IPM Kit LogiCal	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
21.	DPS550263	DPS550263CZ	G.R.I. Double LogiCal Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
22.	DPS560928	DPS560928CZ	Uni Regensburg Zweifach-Druckmebset Rot/Blau	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
23.	DPS562128	DPS562128CZ	KWK Anasthesie	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
24.	DPS563238	DPS563238CZ	Zweifach-Druckmess-Set IT2	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
25.	DPS563244	DPS563244CZ	Zweifach-Druckmess-Set An-Op	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
26.	DPS563517	DPS563517CZ	2-Fach-Set Intensiv	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
27.	DPS565821	DPS565821CZ	2-Fach Monitoring Set Klinikum Saarbrucken	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
28.	DPS565825	DPS565825CZ	Zweifach Druckmess Set Mit Option Uni D	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
29.	DPS565886	DPS565886CZ	Zweifach-Set Druckmessung	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
30.	DPS566336	DPS566336CZ	DPS-Charite 2 Fach Rot/Blau	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
31.	DPS566381	DPS566381CZ	DPS-Oberhavel 2-Fach	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
32.	DPS567002	DPS567002CZ	SMA 2-Fach Rot, Blau	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice. Czech Republic	45760	IIa	2
33.	DPS567041	DPS567041CZ	2-Fach Set Rot Blau Uni Dusseldorf	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
34.	MX9622	MX9622CZ	DPS Double Line Pressure Monitoring Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
35.	MX9622V	MX9622VCZ	DPS Double Line Pressure Monitoring Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
36.	DPS564464	DPS564464CZ	Einfachset Mit Option Marburg	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
37.	DPS561005	DPS561005CZ	Art ZVD Druckmess-Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
38.	DPS562497	DPS562497CZ	Druckmess System	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
39.	DPS563208	DPS563208CZ	Druckmess-Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
40.	DPS564120	DPS564120CZ	Geschlossenes Druckmess-Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
41.	DPS566335	DPS566335CZ	DPS-Charite 1-Fach Rot	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
42.	DPS567001	DPS567001CZ	SMA 1-Fach Rot	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
43.	DPS567047	DPS567047CZ	1-Fach Set Rot Uni Munster	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
44.	DPS567050	DPS567050CZ	AS-Set 180CM Klinikum Singen	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
45.	DPS720789	DPS720789CZ	DPS Single Pressure Mon Line 213CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
46.	MX9604	MX9604CZ	DPS Single Line Pressure Monitoring Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
47.	MX9605	MX9605CZ	DPS Single Line Pressure Monitoring Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2

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48.	MX9624R	MX9624RCZ	DPS Single Line Pressure Monitoring	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
49.	MX9624R-CST	MX9624R-CSTCZ	DPS Pressure Monitoring Secure Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
50.	MX9624RL	MX9624RLCZ	DPS Single Pressure Monitoring Set 180CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
51.	MX9624RV	MX9624RVCZ	DPS Single Line Pressure Monitoring Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
52.	MX9625R	MX9625RCZ	DPS Single Line Pressure Monitoring Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
53.	MX9625R-MAV	MX9625R-MAVCZ	Single Line, MIN Residual Luer Stopcock	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
54.	MX9634B	MX9634BCZ	DPS Venous Pressure Monitoring Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
55.	MX960P1	MX960P1CZ	Pressure Transducer Reusable LogiCal	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	14119	IIb	10
56.	DPS560287	DPS560287CZ	1 Fach Druckmess-Set F, ITV Stat. Rot	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
57.	DPS560288	DPS560288CZ	1 Fach Druckmess-Set F, I TV-Stat Blau	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
58.	DPS562580	DPS562580CZ	Paediatric Monitoring Set AKME Poland	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
59.	DPS563151	DPS563151CZ	HLM-Druckmess-Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2

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60.	DPS563152	DPS563152CZ	Kardioplegie-Druckdom	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
61.	DPS563401	DPS563401CZ	DPS-Set-Art	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
62.	DPS563402	DPS563402CZ	DPS-Set-Ven	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
63.	DPS563973	DPS563973CZ	Druck-Dom-HKL	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
64.	DPS564211	DPS564211CZ	LogiCal Version CR40350.3	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
65.	DPS564898	DPS564898CZ	Monitoring Set LogiCal	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
66.	DPS564963	DPS564963CZ	LogiCal Pressure Monitoring Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
67.	DPS565828	DPS565828CZ	Monitoring Set MZ HTG ANA BLAU	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
68.	DPS565841	DPS565841CZ	Kardio-Technik	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
69.	DPS566311	DPS566311CZ	Monitoring Set 3 Fach	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
70.	MX1450	MX1450CZ	Double LogiCal for Cath Lab	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
71.	MX1452	MX1452CZ	Single LogiCal for Cath Lab	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
72.	MX1960	MX1960CZ	Dome DPS with Two Stopco CKS Red	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
73.	MX1961	MX1961CZ	Dome DPS with Two Stopco CKS Blue	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
74.	MX1962	MX1962CZ	DPS Dome Mit Zwei Dreiwegeh HNEN Weiss	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
75.	MX960SCF	MX960SCFCZ	DPS w/ Stopcock and Flush	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
76.	MX960X2SCP1	MX960X2SCP1CZ	DPS Dome with Two Stopcock	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
77.	MX960XXP1	MX960XXP1CZ	DPS Dome Male/Male	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
78.	MX960XYP1	MX960XYP1CZ	DPS Dome Female/Male	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
79.	MX9630	MX9630CZ	DPS Neonatal Pressure Monitoring Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
80.	DPS550033	DPS550033CZ	Triple Pressure Monitoring Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
81.	DPS561418	DPS561418CZ	Druckmess-Set 2-Fach	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
82.	DPS561603	DPS561603CZ	Klinikum Passa Herz OP/INT 2 Fach ART/ZV	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
83.	DPS561627	DPS561627CZ	DM Set Bad Berka	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
84.	DPS564828	DPS564828CZ	2-Fach-Set Uni Marburg	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
85.	DPS567036	DPS567036CZ	2-Fach-Set Mit Option	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
86.	MX9622VT	MX9622VTCZ	DPS Double Line Press Mon Set w/ Triple Admin	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
87.	MX822-S	MX822-SCZ	Administration Set Double	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice ,Czech Republic	58977	IIa	2
88.	MX823-S	MX823-SCZ	Administration Set Triple	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	58977	IIa	2
89.	MX521R-60ST	MX521R-60STCZ	Stopcock ‘T’ Handle Extension	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
90.	MX521R-70	MX521R-70CZ	Stopcock ‘T’ with Extension	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
91.	MX544RD	MX544RDCZ	Blood Pressure Monitoring Line 120CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
92.	MX545RD	MX545RDCZ	Blood Pressure Monitoring Line 150CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
93.	MX546B	MX546BCZ	Blood Pressure Monitoring 180CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
94.	MX546RD	MX546RDCZ	Blood Pressure Monitoring Line 180CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
95.	MX560P1	MX560P1CZ	Blood Pressure Monitoring Lines 15CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
96.	MX561P1	MX561P1CZ	Blood Pressure Monitoring Line 30CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
97.	MX562P1	MX562P1CZ	Blood Pressure Monitoring Line 60CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
98.	MX564P1	MX564P1CZ	Blood Pressure Monitoring Line 120CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
99.	MX565	MX565CZ	Blood Pressure Monitoring Line 150CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
100.	DPS620666B	DPS620666BCZ	Kit Coro Nantes (Transtar)	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIb	10
101.	SX550141	SX550141CZ	Health Care International Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIb	10
102.	MX9533	MX9533CZ	Kids Kit™ W/DPT & 45CM Mon. Line	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIb	10
103.	MX9504	MX9504CZ	DPT Single Pressure Monitoring Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIb	10
104.	MX9505	MX9505CZ	DPT Single Pressure Monitoring Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIb	10
105.	MX9524R	MX9524RCZ	DPT Single Pressure Monitoring Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIb	10
106.	MX9534B	MX9534BCZ	DPT Single Pressure Monitoring Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIb	10
107.	SX530179	SX530179CZ	Single Pressure Monitoring Line with DPT	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIb	10

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
108.	MX9530	MX9530CZ	DPT Neonatal Pressure Monitoring Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIb	10
109.	SX622043	SX622043CZ	Kit Depression Transtar Pour Injecteur Medrad	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIb	10
110.	MX9522	MX9522CZ	DPT Double Pressure Monitoring Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIb	10
111.	DPS563391	DPS563391CZ	2-Fach Durckmess-Set MIT Option	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
112.	DPS562003	DPS562003CZ	DM-Set-Herzklinik DD	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
113.	DPS563482	DPS563482CZ	DM-Set-CB-HKL	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
114.	DPS562094	DPS562094CZ	LogiCal Triple Pressure Monitoring Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
115.	DPS564960	DPS564960CZ	LogiCal 3-fach Druckmess-Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
116.	DPS561419	DPS561419CZ	Druckmess-Set 3 Fach	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
117.	DPS567009	DPS567009CZ	2-Fach Set MIT 2 Optionen	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
118.	MX9606	MX9606CZ	DPS Triple Line Pressure Monitoring Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
119.	DPS563243	DPS563243CZ	Dreifach-Druckmess-Set AN-OP	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
120.	DPS567042	DPS567042CZ	3-Fach Set Rot Blau Gelb Uni Dusseldorf	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
121.	DPS562632	DPS562632CZ	Monitoring Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
122.	DPS561007	DPS561007CZ	Dreifach-Druckmess-Set A RT-XVD-PULM ANAS	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
123.	DPS562446	DPS562446CZ	Dreifach-Druck-Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
124.	DPS562171	DPS562171CZ	DM-Set Cottbus 4-Fach	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
125.	MX9623VT	MX9623VTCZ	DPS Triple Pressure Monitoring Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
126.	DPS721474	DPS721474CZ	DPS Triple Line Turku Univeristy Hospital	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
127.	DPS567003	DPS567003CZ	SMA 3-Fach Rot, Blau, Gelb	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
128.	DPS566394	DPS566394CZ	3-Fach Herz-Op	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
129.	DPS566334	DPS566334CZ	DPS-Charite 1-Fach Blau	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
130.	DPS560772	DPS560772CZ	Set Kardiotechink Trier	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
131.	DPS566301	DPS566301CZ	3 Fach-Set-Kardiotechnik	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
132.	DPS620688	DPS620688CZ	Kit Pression Cec. Triple	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
133.	DPS563247	DPS563247CZ	3-Fach Druckmess-Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
134.	DPS563253	DPS563253CZ	Vierfach-Druckmess-Set AN-OP	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
135.	DPS565843	DPS565843CZ	Dreifach-Druckmess Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
136.	DPS509523	DPS509523CZ	Pressure Monitoring Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
137.	DPS561009	DPS561009CZ	Dreifach-Druckmess-Set a RT-ZVD-PULM INTE	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
138.	DPS564441MAV	DPS564441MAVCZ	LogiCal 3-Fachset Mav Mit Option, Rot 180CM, Blau 150CM, Gelb 150CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
139.	DPS567066	DPS567066CZ	LogiCal 2-Fach Druckmesset, Rot 150CM, Blau 90CM, Mit Marvelous	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
140.	DPS567089	DPS567089CZ	LogiCal 3-Fach Druckmesset Mit Marvelous, Rot 150Cm Blau & Klar 120CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
141.	DPS566337	DPS566337CZ	DPS-Charite 3-Fach Rot/Blau/Klar	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
142.	DPS563245	DPS563245CZ	Dreifach-Druckmess-Set IT2	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
143.	DPS563518	DPS563518CZ	3-Fach-Set Intensiv	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
144.	DPS565822	DPS565822CZ	3-Fach Monitoring Set Klinikum Saarbrucken	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
145.	DPS563680	DPS563680CZ	Vierfach-Druckmess-Set Uni Regensburg	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
146.	DPS721372	DPS721372CZ	Triple LogiCal Set Yorkhill	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
147.	MX9606VQ	MX9606VQCZ	DPS Triple Pressure Monitoring Set with Quad Admin	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
148.	MX960SCFB	MX960SCFBCZ	DPS W/ Stopcock and Flush (Blue)	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
149.	DPS567092	DPS567092CZ	Monitoring As-Set, Rote Linie 180CM Mit Mav-Verlangerung, Blaue Linie 180CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
150.	SX550193A	SX550193ACZ	Extension Line	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice ,Czech Republic	45760	IIa	2
151.	DPS567081	DPS567081CZ	LogiCal 2-Fach Druckmess Set Mit Marvelous, Rot 210CM, Blau 180CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
152.	DPS721252	DPS721252CZ	Double Pressure Monitoring Set for Milpark Hospital	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
153.	DPS721469	DPS721469CZ	DPS Single Line Pressure Monitoring Turku Univeresity	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
154.	MX521R-70MAV	MX521R-70MAVCZ	Stopcock Extension 15CM Marvelous	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
155.	MX544B	MX544BCZ	Blood Pressure Monitoring Line 120CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
156.	DPS562587	DPS562587CZ	Venoses Druckmess System Verklebt	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
157.	DPS566345	DPS566345CZ	Einfach-Set Mit ZVD	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
158.	DPS566314	DPS566314CZ	Femoralis System	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
159.	MX9601	MX9601CZ	DPS Single Line Pressure Monitoring Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
160.	DPS564905	DPS564905CZ	Monitoring Set LogiCal	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
161.	MX566P1	MX566P1CZ	Blood Pressure Monitoring Line 180CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
162.	DPS566393	DPS566393CZ	DPS-2 Fach Pirna	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
163.	DPS563357	DPS563357CZ	Kardio-Anaesthesie-Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
164.	MX9605V	MX9605VCZ	DPS Single Line Pressure Monitoring Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
165.	DPS550305	DPS550305CZ	DPS Single Line Pressure Monitoring Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
166.	MX545B	MX545BCZ	Blood Pressure Monitoring Line 150CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
167.	DPS720416	DPS720416CZ	DPS Double Line Pressure Monitoring Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
168.	MX9634BV	MX9634BVCZ	DPS Venous Pressure Monitoring Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
169.	MX542RD	MX542RDCZ	Blood Pressure Monitoring Line 60CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
170.	DPS560804	DPS560804CZ	Monitoring Set ABT Anasthesie-Intensiv	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
171.	MX543RD	MX543RDCZ	Blood Pressure Monitoring Line 90CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranic, Czech Republic	45760	IIa	2
172.	DPS720788	DPS720788CZ	DPS Venous Pressure Mon Kit 213CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
173.	DPS550347	DPS550347CZ	Double Pressure Monitoring Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
174.	DPS564217	DPS564217CZ	2-Fach Druckmessung	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
175.	DPS560756	DPS560756CZ	Monitoring Set (Art. ZVD-Druckmebset) Kliniku	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
176.	DPS567049	DPS567049CZ	As Set Rot Uni Munster	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
177.	DPS564929	DPS564929CZ	2 Fach Druckmessung Lukas KRH. Neuss	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
178.	DPS720704	DPS720704CZ	Single LogiCal Set (Red)	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
179.	DPS560754	DPS560754CZ	Kardio Technik Uni Bonn	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
180.	DPS567040	DPS567040CZ	1 – Fach Set Rot Uni Dusseldorf	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
181.	DPS566364	DPS566364CZ	Cottbus ASV	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
182.	MX960X2SC-US	MX960X2SC-USCZ	DPS Dome with Two Stopcocks	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
183.	DPS562717	DPS562717CZ	Druckmess-Set Herne	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
184.	DPS721309	DPS721309CZ	Single Bifurcated LogiCal Set Sunderland	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
185.	DPS566384	DPS566384CZ	DPS-Charite Neo Rot	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
186.	DPS550261	DPS550261CZ	Stirling R.I. Art Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
187.	DPS720710	DPS720710CZ	Double LogiCal Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
188.	MX521R-60	MX521R-60CZ	Stopcock ‘T’ with Extension	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
189.	DPS563392	DPS563392CZ	Option-3-Fach Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
190.	MX9634Y	MX9634YCZ	DPS Pulmonary Pressure Monitoring Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
191.	DPS621907	DPS621907CZ	Kit CEC	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
192.	DPS630181	DPS630181CZ	I.P.M. Kit (Red)	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
193.	DPS567011	DPS567011CZ	Option Set Stuttgart	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
194.	DPS720173	DPS720173CZ	DPS Double Line Pressure Monitoring Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
195.	DPS550197	DPS550197CZ	Raigmore Double Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
196.	MX576P1	MX576P1CZ	Blood Pressure Monitoring Line 180CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
197.	MX9624ASV-CST	MX9624ASV-CSTCZ	DPS Pressure Monitoring Secure Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
198.	DPS564133	DPS564133CZ	2-Fach Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
199.	DPS566338	DPS566338CZ	DPS-Charite HKL	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
200.	MX567P1	MX567P1CZ	Blood Pressure Monitoring Line 210CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
201.	DPS562909	DPS562909CZ	HKL Druckmess-Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
202.	DPS564850	DPS564850CZ	Druckmess-Set Arteriell/Venos	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
203.	DPS550196	DPS550196CZ	Raigmore Single IPM Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
204.	DPS563254	DPS563254CZ	Art. Druckmess-Set IT2	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
205.	DPS564439MAV	DPS564439MAVCZ	LogiCal 1-Fachset Mav Mit Option, Mit Option, Klar 180CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
206.	DPS564440MAV	DPS564440MAVCZ	LogiCal 2-Fachset Mav Mit Option, Rot 180CM, Blau 150CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
207.	DPS567054	DPS567054CZ	LogiCal 1-Fach Anti-Shunt Druckmess Set 180CM Rot Marvelous	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
208.	DPS567065	DPS567065CZ	LogiCal 1-Fach Erganzungs-Druckmess Set, Gelb 30CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
209.	DPS567091	DPS567091CZ	Einfach Set 180CM Neutral Stadtspital Triemeil ZRH	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
210.	DPS567062	DPS567062CZ	LogiCal 1- Fach Druckmess Set Mit Marvelous, Rot 150CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
211.	DPS567063	DPS567063CZ	LogiCal 1- Fach Druckmess Set Mit, Blau 150CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
212.	DPS567064	DPS567064CZ	LogiCal 1- Fach Druckmess Set Gelb 150CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
213.	DPS567080	DPS567080CZ	LogiCal 2- Fach Druckmess Set Mit Marvelous Uniklinikum Essen	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
214.	DPS567096	DPS567096CZ	LogiCal 2-Fach Druckmess Set Mit Marvelous Rot 210CM, Blau 210CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
215.	DPS567097	DPS567097CZ	LogiCal 1-Fach, Druckmess Set 210CM Rot Mit Marvelous	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
216.	DPS567100	DPS567100CZ	LogiCal 1-Fach, Anti-Shunt Drukmess Set, 180CM Rot Mit 150CM Blau	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
217.	SX567090	SX567090CZ	Monitoring Add On Set, Blaue Linie, 180CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
218.	DPS567074	DPS567074CZ	LogiCal 1-Fach, Anti Shunt Druckmess Set, 210CM Rot, 180CM Blau	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
219.	DPS567075	DPS567075CZ	LogiCal 1-Fach, Anti-Shunt, 210CM Rot Mit Marvelous, 180CM Blau	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
220.	DPS567077	DPS567077CZ	LogiCal 1-Fach, Druckmess Set, 210CM Rot Mit Marvelous	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
221.	DPS567084	DPS567084CZ	1-Fach Set Rote Linie 150CM Mav 30CM Verlaengerung	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
222.	DPS567085	DPS567085CZ	2-Fach LogiCal Rote Linie 150CM Mit Mav Verlaengerung Blau 150CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
223.	DPS567086	DPS567086CZ	1-Fach Set Rote Linie 150CM Mav 30CM Verlaengerung Blau 150CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
224.	DPS567087	DPS567087CZ	LogiCal 1-Fach, Anti-Shunt, 180CM Rot Mit Marvelous, 150CM Blau	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
225.	DPS567088	DPS567088CZ	LogiCal 2-Fach Druckmess Set Mit Marvelous, Rot 150CM, Blau 120	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
226.	DPS567093	DPS567093CZ	LogiCal 2-Fach Druckmess Set Mit Marvelous, Rot 210CM, Blau 210CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
227.	DPS567094	DPS567094CZ	LogiCal 1-Fach, Anti-Shunt 210CM Rot Mit Marvelous, 210CM Blau	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
228.	DPS567095	DPS567095CZ	LogiCal 1-Fach Druckmess Set, 210CM Rot Mit Marvelous	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
229.	DPS567069	DPS567069CZ	LogiCal 1-Fach Mit Doppel Mav Rot 120CM + 70CM Uniklinikum Frankfurt	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
230.	DPS567070	DPS567070CZ	LogiCal 1-Fach Antishunt Mitdoppel Mav Rot 120CM + 70CM Blau 150CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
231.	DPS567067	DPS567067CZ	LogiCal 1-Fach, Druckmess Set, 180CM Rot Mit Marvelous	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
232.	DPS567068	DPS567068CZ	LogiCal 1-Fach, Anti-Shunt, 180CM Rot Mit Marvelous, 150CM Blau	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
233.	MX534-70RD	MX534-70RDCZ	Stopcock with Extension	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
234.	DPS563339	DPS563339CZ	Uni Essen Ven. Druckmess Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
235.	DPS620903	DPS620903CZ	Kit Urodynamique	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
236.	DPS560872	DPS560872CZ	DPS Monitoring Set KH Ludenscheid	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
237.	DPS570411	DPS570411CZ	ICU Kit A	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
238.	SX561048	SX561048CZ	Verlangerung, Drucksystem	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
239.	DPS565827	DPS565827CZ	Monitoring Set MZ HTG ANA Weiss	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
240.	DPS565838	DPS565838CZ	Einfach Druckmess-Set Universal Uni D	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
241.	MX540RD	MX540RDCZ	Blood Pressure Monitoring Line 15CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
242.	DPS560866	DPS560866CZ	DPS Druckmess-Set Klinikum Rechts Der Isar	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
243.	DPS550293	DPS550293CZ	Ayr Renal LogiCal Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
244.	MX821-S	MX821-SCZ	Administration Set.	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	58977	IIa	2
245.	DPS720415	DPS720415CZ	DPS Single Line Pressure Monitoring Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
246.	DPS550262	DPS550262CZ	Stirling R.I. CVP Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
247.	MX563P1	MX563P1CZ	Blood Pressure Monitoring Line 90CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
248.	MX9622-MAV	MX9622-MAVCZ	Double Line Blue/Red Mini-Residual Leur Stopcock	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
249.	DPS561811	DPS561811CZ	Druckmess Set HKL	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
250.	DPS567048	DPS567048CZ	2-Fach Set Rot Blau Uni Munster	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
251.	MX540B	MX540BCZ	Blood Pressure Monitoring Line 15CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
252.	DPS563679	DPS563679CZ	Kardio-Druck	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
253.	DPS540367	DPS540367CZ	Pressure Monitoring Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
254.	DPS566395	DPS566395CZ	1-Fach Herz Op	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
255.	DPS567034	DPS567034CZ	HKL Gehrden	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
256.	DPS566369	DPS566369CZ	DPS-Zweifach CB	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
257.	DPS563043	DPS563043CZ	DPS Druckmess-Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
258.	DPS562997	DPS562997CZ	Art Druckmessung Mit ZVD Geschl System	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
259.	DPS721308	DPS721308CZ	Single LogiCal Set Sunderland	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
260.	DPS720862	DPS720862CZ	Neonatal Pressure Monitoring Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
261.	MX556RD	MX556RDCZ	Blood Pressure Monitoring Line 180CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
262.	MX554B	MX554BCZ	Blood Pressure Monitoring Line 120CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
263.	DPS720705	DPS720705CZ	Single LogiCal Set (Blue)	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
264.	DPS564440	DPS564440CZ	2-Fach Set Uni Gottingen	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
265.	DPS509748	DPS509748CZ	LogiCal Dome M. Spuelsystem	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
266.	DPS566340	DPS566340CZ	DPS-Charite Add on PA	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
267.	DPS567014	DPS567014CZ	Druckdom LogiCal HKL	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
268.	DPS563690	DPS563690CZ	Feschlossenes Druckmess-Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
269.	MX521B-60	MX521B-60CZ	Stopcock 'T' with Extension	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
270.	DPS565820	DPS565820CZ	1-Fach Monitoring Set Klinikum Saarbrucken	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
271.	MX572P1	MX572P1CZ	Blood Pressure Monitoring Line 60CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
272.	DPS567000	DPS567000CZ	1-Fach-Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
273.	DPS565844	DPS565844CZ	IBPM Kit Single for University Krakow	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
274.	DPS564469	DPS564469CZ	Druckmess Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
275.	MX541RD	MX541RDCZ	Blood Pressure Monitoring Line 30CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
276.	DPS567061	DPS567061CZ	LogiCal Single Kit Red, St. Marien Hospital Lunen	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
277.	DPS566390	DPS566390CZ	As-Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
278.	DPS564920	DPS564920CZ	Druckmess-Set Neonatologie Frankf Hoec	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
279.	DPS563235	DPS563235CZ	Uni Essen Druckmess-Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
280.	DPS509929	DPS509929CZ	DPS Monitoring Set Arteric+ZVD OP+Intens	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
281.	MX663P1	MX663P1CZ	Pressure Line Low Vol (Polyethylene) 90CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
282.	DPS566378	DPS566378CZ	Einfachset Antishunt 180CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
283.	DPS565533	DPS565533CZ	Ergaenzungs Set Bad Rothenfelde	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
284.	DPS620788	DPS620788CZ	Set Injection	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
285.	MX577	MX577CZ	Blood Pressure Monitoring Line 213CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
286.	DPS563150	DPS563150CZ	IABP-Druckmess-Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
287.	DPS562445	DPS562445CZ	Zweifach-Druck-Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
288.	DPS561602	DPS561602CZ	Dulm Druckmess-Set 1 Fach	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
289.	DPS565899	DPS565899CZ	Druckmess Set Einfach Venos	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
290.	DPS550313	DPS550313CZ	DPS Double Pressure Monitoring Line	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
291.	MX960FR	MX960FRCZ	LogiCal Dome with Trigger Flush	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
292.	MX546Y	MX546YCZ	Blood Pressure Monitoring Line 180CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
293.	DPS564151	DPS564151CZ	Einfach Druckmess Set- Rot. Neonatalogie	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
294.	SX560413	SX560413CZ	Monitoring Schlauch Kard Iotechnik Bad	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
295.	DPS562321	DPS562321CZ	Druckmess-Set IABP	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
296.	MX571P1	MX571P1CZ	Blood Pressure Monitoring Line 30CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
297.	DPS560974	DPS560974CZ	Monitoring Set Tisch.2.	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
298.	MX573P1	MX573P1CZ	Blood Pressure Monitoring Line 90CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
299.	DPS620839A	DPS620839ACZ	Kit Dilatation	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
300.	DPS562444	DPS562444CZ	Einfach-Druck-Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
301.	SX622044	SX622044CZ	Supplementary Tubing St Nazaire	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
302.	DPS563358	DPS563358CZ	Pap-Linie	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
303.	DPS620703	DPS620703CZ	Kit Coro Pression	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
304.	DPS567201	DPS567201CZ	Mark 910 LogiCal	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
305.	MX544Y	MX544YCZ	Blood Pressure Monitoring Line 120CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
306.	MX9624AS-CST	MX9624AS-CSTCZ	DPS Pressure Monitoring Secure Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
307.	SX550193B	SX550193BCZ	Extension Lines	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
308.	DPS721429	DPS721429CZ	Double Pressure Monitoring Set Pennine Acute Hospitals	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
309.	DPS721430	DPS721430CZ	Single LogiCal Pressure Monitoring Set Pennine Acute Hospitals	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
310.	DPS530789	DPS530789CZ	Kids Kit Neonatal	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
311.	DPS550084	DPS550084CZ	Crosshouse Single Pressure Monitoring	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
312.	DPS550312	DPS550312CZ	DPS Single Line Pressure Monitoring Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
313.	DPS562398	DPS562398CZ	Druckmess Set Oint	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
314.	MX9634BL	MX9634BLCZ	DPS Venous Pressure Monitoring Kit 180CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
315.	MX950SCFR	MX950SCFRCZ	DPT w/ Stopcock and Flush (Red)	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIb	10
316.	SX621665	SX621665CZ	Kit Pression de Coro	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIb	10
317.	SX620316	SX620316CZ	Set de Pression UU Admin Set Leur Lock	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIb	10
318.	MX950P1	MX950P1CZ	TranStar Dpt	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIb	10
319.	SX550084	SX550084CZ	Single Dpt Pressure Monitoring	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIb	10
320.	SX720333	SX720333CZ	Single TranStar Set Freemans	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIb	10
321.	MX9501	MX9501CZ	Dpt Single Pressure Monitoring Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIb	10
322.	DPS621516B	DPS621516BCZ	Kit Cardio Ouvert	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	10
323.	SX550113	SX550113CZ	Double Pressure Monitoring Set for Crosshouse	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIb	10

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
324.	SX620317	SX620317CZ	Set de Pression/UU/Secure/Admin Set Luer	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIb	10
325.	SX650061	SX650061CZ	Paediatric Pressure Monitoring Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIb	10
326.	MX950LP1	MX950LP1CZ	TranStar® Press Trans w/ 152CM Cables	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIb	10
327.	SX562059	SX562059CZ	Druckmess-Set Anasthesie -Intensiv	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIb	10
328.	MX9524-AS	MX9524-ASCZ	Dpt Antishunt Pressure Monitoring Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIb	10
329.	DPS564441	DPS564441CZ	3-Fach Set Uni Gottingen	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
330.	MX921NFC2	MX921NFC2CZ	Blunt Cannula w/ One Way Stopcock	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
331.	DPS566302	DPS566302CZ	1 Fach-Set-Kardiotechnik	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
332.	DPS560714	DPS560714CZ	Sonderanfertigung Klinikum Aschaffenburg	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
333.	DPS564463	DPS564463CZ	Options Set Marburg	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
334.	DPS566324	DPS566324CZ	Neonat. Set Ater.Verlang Nicht Verklebt	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
335.	DPS566385	DPS566385CZ	DPS-Charite Neo Blau	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2

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336.	DPS567035	DPS567035CZ	HKL Gehrden Options Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
337.	DPS567071	DPS567071CZ	Single Pressure Monitoring Kit Volmarstei	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
338.	DPS567073	DPS567073CZ	LogiCal 1- Fach Druckmess, 180CM Rot Mit Marvelous	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
339.	DPS622049	DPS622049CZ	SET De Pression Simple Rouge for Ch Mignot	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
340.	DPS721395	DPS721395CZ	Pressure Monitoring Set for Wilmed Park	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
341.	MX543B	MX543BCZ	Blood Pressure Monitoring Line 90CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
342.	MX563-PT	MX563-PTCZ	Blood Pressure Monitoring Line 90CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
343.	MX568P1	MX568P1CZ	96IN (244CM) Monitoring Line	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
344.	MX574P1	MX574P1CZ	Blood Pressure Monitoring Line 120CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
345.	MX664P1	MX664P1CZ	Pressure Line Low Vol (Polyethylene)120CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
346.	MX950X2SCP1	MX950X2SCP1CZ	TranStar Dpt W/ Two Stopcocks	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIb	10
347.	MX960SCN	MX960SCNCZ	Dps Dome w/ Stopcock and Neonatal Flush	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
348.	SX550260	SX550260CZ	Simpsons Neo Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIb	10
349.	SX600240	SX600240CZ	Paediatric Pressure Monitoring Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIb	10
350.	DPS560517	DPS560517CZ	Zweifach Druckmess-Set Hz Brandenburg	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
351.	DPS560803	DPS560803CZ	Marien Hospital Wesel Hk L-Druckmess-Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
352.	DPS564152	DPS564152CZ	Einfach Druckmessset- Blau Neonatologie	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
353.	DPS564245	DPS564245CZ	Druckmess-Set Art.- Venos (210CM)	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
354.	DPS564439	DPS564439CZ	1-Fach Set Uni Gottingen	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
355.	DPS566375	DPS566375CZ	Zweifachset	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
356.	DPS566379	DPS566379CZ	Einfachset Antishunt 210CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
357.	DPS567038	DPS567038CZ	Druckmesset Einfach Mit ZVD	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
358.	DPS721410	DPS721410CZ	Double LogiCal Pressure Monitoring Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
359.	MX463	MX463CZ	Press Mon Line (Polyethylene) 90CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
360.	MX553B	MX553BCZ	Blood Pressure Monitoring Line 90CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
361.	MX920NFC2	MX920NFC2CZ	Needle Free Adaptor Hemodraw	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
362.	MX922NFC2	MX922NFC2CZ	Blunt Cannula with Vacuum Tube Holder	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
363.	MX923NFC2	MX923NFC2CZ	Blunt Cannula w/ Stopcock	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
364.	MX9506-CST	MX9506-CSTCZ	Dpt Triple Line Pressure Monitoring Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIb	10
365.	MX9602	MX9602CZ	DPS Double Line Pressure Monitoring Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
366.	DPS567120	DPS567120	LogiCal 1-Fach Anti Shunt Mit Doppel MAV	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
367.	DPS567121	DPS567121	LogiCal 2-Fach Druckmesset Mit Marvelous	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
368.	DPS567122	DPS567122	LogiCal 1-Fach Add-On Mit Marvelous, Rot 150CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
369.	DPS567123	DPS567123	LogiCal 1-Fach Add-On Mit Marvelous, Gelb 150CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
370.	DPS561418MAV	DPS561418MAV	LogiCal Doppel Kit 150CM Klare Linie Mit Mav, 150CM Klare Linie Mit Opt	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
371.	DPS561419MAV	DPS561419MAV	LogiCal Triple Kit 150CM Klare Linie Mit Mav, 2 X 150CM Klare Linie Mit Opt	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
372.	DPS567102	DPS567102	LogiCal 1-Fach Druckmess Set 210CM Rot	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
373.	DPS567103	DPS567103	LogiCal 2-Fach Druckmess Set Rot 180CM Blau 180CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
374.	DPS567104	DPS567104	LogiCal 2-Fach Druckmes Set Rot 210CM Blau 180CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
375.	DPS567105	DPS567105	LogiCal 1-Fach, Druckmess Set, 180CM Rot Mit Marvelous	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
376.	DPS567106	DPS567106	LogiCal 1-Fach, Druckmess Set 210CM Rot Mit Marvelous	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
377.	DPS567107	DPS567107	LogiCal 2-Fach Druckmess Set Mit Marvelous Rot 180CM Blau 180CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
378.	DPS567108	DPS567108	LogiCal 2-Fach Druckmess Set Mit Marvelous Rot 210CM Blau 180CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
379.	DPS567109	DPS567109	LogiCal 1-Fach, Anti-Shunt Druckmess Set 180CM Rot Mit Marvelous 180CM Blau	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
380.	DPS567110	DPS567110	LogiCal 1-Fach, Anti-Shunt Druckmess Set Rot 180CM Blau 180CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
381.	DPSHC0002	DPSHC0002	3-Fach LogiCal Rote Linie 150CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
382.	DPSHC0019	DPSHC0019	LogiCal 1-Fach Druckmess Set 180cm Klare Linie	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
383.	DPSHC0007	DPSHC0007	Set De Pression Simple Chu Grenoble	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
384.	DPSHC0008	DPSHC0008	Set De Pression Double Antishunt Chu Grenoble	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
385.	DPSHC0022	DPSHC0022	LogiCal 1-Fach, Anti-Shunt Durckmess Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
386.	DPSHC0018	DPSHC0018	DPS550305 - Single Red	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
387.	DPSHC0029	DPSHC0029	LogiCal 1-Fach Option Set Mit 150CM Blauer Linie	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
388.	DPSHC0030	DPSHC0030	LogiCal 1-Fach Option Set Mit 150CM Blauer Linie	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
389.	DPSHC0031	DPSHC0031	LogiCal 1-Fach Druckmess Set Blau Mit Linie Klar 120CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
390.	DPSHC0037	DPSHC0037	LogiCal Dome Mit 2 Haehnen	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
391.	DPSHC0039	DPSHC0039	LogiCal 1-fach Anti Shunt rot 120cm+ 70 cm, blau 150cm	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
392.	DPSHC0040	DPSHC0040	LogiCal Anti Shunt Druckmess Set,120CM Plus 70CM Rot Mit 2x Mav,150CM Blau	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
393.	DPSHC0041	DPSHC0041	LogiCal Anti Shunt Druckmess-Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
394.	DPSHC0042	DPSHC0042	LogiCal 3-Ach Druckmess-Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
395.	DPSHC0043	DPSHC0043	LogiCal 3-Ach Druckmess-Set 1	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
396.	DPSHC0047	DPSHC0047	LogiCal® Single Monitoring Kit with 2-Marvelous Bwzk	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
397.	DPSHC0048	DPSHC0048	LogiCal® Double Monitoring Kit with Option And 2-Marvelous Bwzk	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
398.	DPSHC0049	DPSHC0049	Stopcock Extension 30CM with Marvelous Bwzk	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
399.	DPSHC0056	DPSHC0056	Blue Single IBPM Set with Stopcock Extension	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
400.	DPSHC0087	DPSHC0087	Kinder 3-Fach Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
401.	DPSHC0070	DPSHC0070	Liverpool H&C Single Aterial Line (Red)	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
402.	DPSHC0085	DPSHC0085	Admin Set Heidelberg	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
403.	DPSHC0086	DPSHC0086	Options Set Heidelberg	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
404.	DPSHC0013	DPSHC0013	LogiCal Anti-Shunt Druckmess-Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
405.	DPSHC0014	DPSHC0014	LogiCal 2-Fach Druckmess-Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
406.	DPSHC0020	DPSHC0020	Triple LogiCal Set Liverpool Heart & Chest	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
407.	DPSHC0046	DPSHC0046	Anti-Shunt-Hermetics-Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
408.	DPSHC0076	DPSHC0076	CBSS 2-fach Druckmessset Mit Option	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
409.	DPSHC0081	DPSHC0081	CBSS 5 ML, Antishunt Proximaler Entnahmeport 60 CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
410.	DPSHC0082	DPSHC0082	CBSS 5 ML, Dreifach Proximaler Entnahmeport 60 CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
411.	DPSHC0083	DPSHC0083	CBSS 5 ML, Einfach Proximaler Entnahmeport 60 CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
412.	DPSHC0084	DPSHC0084	CBSS 5 ML, Zweifach Proximaler Entnahmeport 60 CM	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
413.	DPSHC0090	DPSHC0090	CBSS-5ML Zweifach Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
414.	DPSHC0091	DPSHC0091	CBSS-5ML, Antishunt Set, (172/15cm)	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
415.	DPSHC0092	DPSHC0092	CBSS-5ML, Triple Set, (172/15cm)	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
416.	DPSHC0093	DPSHC0093	CBSS-5ML, Single Set, (172/15CM)	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
417.	DPSHC0094	DPSHC0094	CBSS-5ML, Double Set, (172+15cm)	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
418.	DPS563829	DPS563829CZ	Paed Druckmessung	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice, Czech Republic	45760	IIa	2
419.	MX401G151P1	MX401G151P1	Smiths Medical 5ml Blood Sampling 152cm Add On Kit, Arm Mounted	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIa	2

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
420.	MX961E181P1	MX961E181P1	Logical 183cm 1-Line 5ml Blood Sampling Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIa	2
421.	MX961E211P1	MX961E211P1	Logical 213cm Single Line 5ml Blood Sampling Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIa	2
422.	MX961G181P1	MX961G181P1	Logical 183cm 1-Line 5ml Blood Sampling Kit Arm Mount	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIa	2
423.	MX962E181P1	MX962E181P1	Logical 183cm 2-Line 5ml Blood Sampling Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIa	2
424.	MX962E211P1	MX962E211P1	Logical 213cm 2-Line 5ml Blood Sampling Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIa	2
425.	MX962G181P1	MX962G181P1	Logical 183cm 2-Line 5ml Blood Sampling Kit Arm Mount	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIa	2
426.	MX963E181P1	MX963E181P1	Logical 183cm 3-Line 5ml Blood Sampling Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIa	2
427.	MX963E211P1	MX963E211P1	Logical 213cm 3-Line 5ml Blood Sampling Kit	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIa	2
428.	MX96AE181P1	MX96AE181P1	Logical 183cm 1-Line 5ml Blood Sampling Kit With Anti Shunt Stopcock	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIa	2
429.	MX96AE211P1	MX96AE211P1	Logical 213cm 1-Line 5ml Blood Sampling Kit With Anti Shunt Stopcock	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIa	2

Appendix 2: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
15	Updated to newest DoC template version (002) and addition of applicable codes for EU market authorization	Breanna Fautsch	21-SEP-2016
16	Updated the EC certificate reference to the most current version released in Agile	Breanna Fautsch	04-OCT-2016
17a	Updated to include LogiCal Sampling kit devices for release in Smiths-Medical DACH region (Germany, Austria, Switzerland).	Bruce Backlund	26-JAN-2017
17b	Remove codes that were added as a part of Revision 15. This was not the correct DoC for those codes. Added 3 new applicable codes.	Bruce Backlund	14-MAR-2017
18	Update to include Hemodraw TranStar/Logical CBSS EU devices	Bruce Backlund	21-MAR-2017
19	Update to include custom kit DPSHC0056	Bruce Backlund	10-APR-2017
20	Changed the Effective By date, updated formatting to better fit information on page, re-numbered the “num” column as it was improperly numbered. Changed document number format from SXXX to DoC-XXX to load documents into Agile. Removed SKUs as they don’t belong to this Technical File SKUs moved to S1067: MX401H152P1, MX951H182P1, MX952H182P1, MX953H182P1, MX95AH182P1, MX961H182P1, MX961H212P1, MX962H182P1, MX962H212P1, MX963H182P1, MX96AH182P1, MX96AH212P1, DPSHC0056.	Manasa Boppana/ Mikael Evans	05-JUN-2017
021	Removed SKU DPS567124 as this SKU could not be found in Agile or Oracle as an active product. Changed manufacturing site from “MCZH” to the Czech manufacturing site address.	Stacy Novak	30-JUN-2017
022	Removed the following SKUs because they were incorrectly placed on this DoC and were moved to DoC-070: MX9633CZ, MX9636CZ, MX9637-LTCZ, MX961E181P1, MX961G181P1, MX962E181P1, MX962G181P1, MX963E181P1,	Mitchell Madsen	03-OCT-2017

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
	MX401G151P1, MX96AE211P1, MX961E211P1, MX962E211P1, MX963E211P1, MX9634CZ, DPS564461CZ, SX566383CZ, MX818CZ, DPS563829CZ, DPS564137CZ, MX8036CZ, and DPS564258CZ. Also, removing code DPS550219CZ due to being Obsolete. Added the code DPSHC0056 that was incorrectly placed on DoC-070. Removed the following Class I SKUs to DoC-089 to keep Classes separate: MX4810P1CZ, MX4705P1CZ, MX4710P1CZ, MX261P1CZ, MX240P1CZ, MX1821-GCZ, MX260CZ, MX262P1CZ, MX260-PMCZ, MX244P1CZ, MX4830P1CZ, MX4806CZ, MX800P1CZ, MX264CZ, MX263P1CZ, MX267C2CZ, MX241P1CZ, MX800-SCZ.		
123	Added the following codes, DPSHC0056, DPSHC0081, DPSHC0082, DPSHC0083, DPSHC0084, DPSHC0087, DPSHC0070, DPSHC0085, DPSHC0086, DPSHC0076, DPSHC0090, DPSHC0091, DPSHC0092, DPSHC0093, DPSHC0094 due to being legally manufactured by Hranice, rather than Grasbrunn and due to being in alignment with the product scope of this DoC. Additionally the DoC template has been updated to the current released rev. 003 of the document. Per DVSOP2005 revision format for production documents follows a 1## format. No revisions were skipped from revision 022 to 123.	Dominique Neisz	19-OCT-2018
124	Added the following codes, DPSHC0013, DPSHC0014, DPSHC0020, due to being legally manufactured by Hranice, and previously not identified as affected products to be added on revision 123. Removed the following SKU's: DPSHC0096, MX96AE181Pa, DPSHC0076, DPSHC0081, DPSHC0082, DPSHC0083, DPSHC0084, DPSHC0090, DPSHC0091, DPSHC0092, DPSHC0093, and DPSHC0094 due to falling under S1067 as Medex™ closed blood sampling products. DPS567050CZ and SX509748CZ were identified as duplicate SKU's on the DoC and were removed. MX961Z42P1CZ and MX962Z74P1CZ were removed due to being captured on	Dominique Neisz	12-DEC-2018

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
	DoC-255. Coverage of orphaned EC Certificate referenced on title page is provided by Czech Competent Authority SUKL.		
125	Updated to the latest template revision (from 003 to 105). Changed the STED title from "Invasive Blood Pressure Monitoring" to "Invasive Patient Pressure Monitoring Devices and Accessories" 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 “LogiCal® pressure transducers” as a Tradename to reflect the LogiCal products listed. Changed the Notified Body from Intertek AMTAC to BSI and the EC Certificate from 1201-09 A to CE 669121 as the Notified Body for the SKUs on this DoC has changed from AMTAC to BSI. Split the "Catalog Number" column into two -- "External Reference Number" and "Internal Reference Number" to account for the CZ and non-CZ codes. Revised the Product Descriptions to align with the descriptions in Agile. Changed GMDN Code for SKUs DPS620666BCZ, SX550141CZ, MX9533CZ, MX9504CZ, MX9505CZ, MX9524RCZ, MX9534BCZ, SX530179CZ, MX9530CZ, SX622043CZ, MX9522CZ, MX950SCFRCZ, SX621665CZ, SX620316CZ, MX950P1CZ, SX550084CZ, SX720333CZ, MX9501CZ, SX550113CZ, SX620317CZ, SX650061CZ, MX950LP1CZ, SX562059CZ, MX9524-ASCZ, MX950X2SCP1CZ, SX550260CZ, SX600240CZ, and MX9506-CSTCZ, from 35927 to 45760 to better align with SKUs.	Alicia Wilson	30-AUG-2019

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
	Changed GMDN Code for DPS562296CZ, DPS564134CZ, DPS564212CZ, DPS564833CZ, DPS564928CZ, DPS565837CZ, DPS565873CZ, DPS566307CZ, DPS566329CZ, DPS566339CZ, DPS566387CZ, DPS566388CZ, DPS566391CZ, DPS567007CZ, MX9624ASCZ, MX9624ASVCZ, MX9624ASVLTCZ, MX9624ASVLT-MAVCZ, MX9625ASCZ, DPS550143CZ, DPS550263CZ, DPS560928CZ, DPS562128CZ, DPS563238CZ, DPS563244CZ, DPS563517CZ, DPS565821CZ, DPS565825CZ, DPS565886CZ, DPS566336CZ, DPS566381CZ, DPS567002CZ, DPS567041CZ, MX9622CZ, MX9622VCZ, DPS564464CZ, DPS561005CZ, DPS562497CZ, DPS563208CZ, DPS564120CZ, DPS566335CZ, DPS567001CZ, DPS567047CZ, DPS567050CZ, DPS720789CZ, MX9604CZ, MX9605CZ, MX9624RCZ, MX9624R-CSTCZ, MX9624RLCZ, MX9624RVCZ, MX9625RCZ, MX9625R-MAVCZ, MX9634BCZ, DPS560287CZ, DPS560288CZ, DPS562580CZ, DPS563151CZ, DPS563152CZ, DPS563401CZ, DPS563402CZ, DPS563973CZ, DPS564211CZ, DPS564898CZ, DPS564963CZ, DPS565828CZ, DPS565841CZ, DPS566311CZ, MX1450CZ, MX1452CZ, MX1960CZ, MX1961CZ, MX1962CZ, MX960SCFCZ, MX960X2SCP1CZ, MX960XXP1CZ, MX960XYP1CZ, MX9630CZ, DPS550033CZ, DPS561418CZ, DPS561603CZ, DPS561627CZ, DPS564828CZ, DPS567036CZ, MX9622VTCZ, MX544RDCZ, MX545RDCZ, MX546BCZ, MX546RDCZ, MX560P1CZ, MX561P1CZ, MX562P1CZ, MX564P1CZ MX565CZ, DPS563482CZ, DPS562094CZ, DPS564960CZ, DPS561419CZ, DPS567009CZ, MX9606CZ, DPS563243CZ, DPS567042CZ, DPS562632CZ, DPS561007CZ, DPS562446CZ, DPS562171CZ, MX9623VTCZ, DPS721474CZ, DPS567003CZ, DPS566394CZ, DPS566334CZ, DPS560772CZ, DPS566301CZ,		

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
	DPS620688CZ, DPS563247CZ, DPS563253CZ, DPS565843CZ DPS509523CZ, DPS561009CZ, DPS564441MAVCZ, DPS567066CZ, DPS567089CZ, DPS566337CZ, DPS563245CZ, DPS563518CZ, DPS565822CZ, DPS563680CZ, DPS721372CZ, MX9606VQCZ, MX960SCFBCZ, DPS567092CZ, SX550193ACZ, DPS567081CZ, DPS721252CZ, DPS721469CZ, MX521R-70MAVCZ, MX544BCZ, DPS562587CZ, DPS566345CZ, DPS566314CZ, MX9601CZ, DPS564905CZ, MX566P1CZ, DPS566393CZ, DPS563357CZ, MX9605VCZ, DPS550305CZ, MX545BCZ, DPS720416CZ, MX9634BVCZ, MX542RDCZ, DPS560804CZ, MX543RDCZ DPS720788CZ, DPS550347CZ, DPS564217CZ, DPS560756CZ, DPS567049CZ, DPS564929CZ, DPS720704CZ, DPS560754CZ, DPS567040CZ, DPS566364CZ, MX960X2SC-USCZ, DPS562717CZ, DPS721309CZ, DPS566384CZ, DPS550261CZ, DPS720710CZ, MX521R-60CZ, DPS563392CZ, MX9634YCZ, DPS621907CZ, DPS630181CZ, DPS567011CZ, DPS720173CZ, DPS550197CZ, MX576P1CZ, MX9624ASV-CSTCZ, DPS564133CZ, DPS566338CZ, MX567P1CZ, DPS562909CZ, DPS564850CZ, DPS550196CZ, DPS563254CZ, DPS564439MAVCZ, DPS564440MAVCZ, DPS567054CZ, DPS567065CZ, DPS567091CZ, DPS567062CZ, DPS567063CZ, DPS567064CZ, DPS567080CZ, DPS567096CZ, DPS567097CZ, DPS567100CZ, SX567090CZ, DPS567074CZ, DPS567075CZ, DPS567077CZ, DPS567084CZ, DPS567085CZ, DPS567086CZ, DPS567087CZ, DPS567088CZ, DPS567093CZ, DPS567094CZ, DPS567095CZ, DPS567069CZ, DPS567070CZ, PS567067CZ, DPS567068CZ, MX534-70RDCZ, DPS563339CZ, DPS620903CZ, DPS560872CZ, DPS570411CZ,		

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
	SX561048CZ, DPS565827CZ, DPS565838CZ, MX540RDCZ, DPS560866CZ, DPS550293CZ, DPS720415CZ, DPS550262CZ, MX563P1CZ, MX9622-MAVCZ, DPS561811CZ, DPS567048CZ, MX540BCZ, DPS563679CZ, DPS540367CZ DPS566395CZ, DPS567034CZ, DPS566369CZ, DPS563043CZ, DPS562997CZ, DPS721308CZ, DPS720862CZ, MX556RDCZ, MX554BCZ, DPS720705CZ, DPS564440CZ, DPS509748CZ, DPS566340CZ, DPS567014CZ, DPS563690CZ, MX521B-60CZ, DPS565820CZ, MX572P1CZ, DPS567000CZ, DPS565844CZ, DPS564469CZ, MX541RDCZ, DPS567061CZ, DPS566390CZ, DPS564920CZ, DPS563235CZ, DPS509929CZ, MX663P1CZ, DPS566378CZ, DPS565533CZ, DPS620788CZ, MX577CZ, DPS563150CZ, DPS562445CZ, DPS561602CZ, DPS565899CZ, DPS550313CZ, MX960FRCZ, MX546YCZ, DPS564151CZ, SX560413CZ, DPS562321CZ, MX571P1CZ, DPS560974CZ, MX573P1CZ, DPS620839ACZ, DPS562444CZ, SX622044CZ, DPS563358CZ, DPS620703CZ, DPS567201CZ, MX544YCZ, MX9624AS-CSTCZ, SX550193BCZ, DPS721429CZ, DPS721430CZ, DPS530789CZ, DPS550084CZ, DPS550312CZ, DPS562398CZ MX9634BLCZ, MX9634BLCZ, DPS621516BCZ, DPS564441CZ, MX921NFC2CZ, DPS566302CZ, DPS560714CZ, DPS564463CZ, DPS566324CZ, DPS566385CZ, DPS567035CZ, DPS567071CZ DPS567073CZ, DPS622049CZ, DPS721395CZ, MX543BCZ, MX563-PTCZ, MX568P1CZ, MX574P1CZ, MX664P1CZ, MX960SCNCZ, DPS560517CZ, DPS560803CZ, DPS564152CZ, DPS564245CZ, DPS564439CZ, DPS566375CZ, DPS566379CZ, DPS567038CZ, DPS721410CZ, MX463CZ, MX553BCZ, MX922NFC2CZ, MX923NFC2CZ, MX9602CZ, DPS567120, DPS567121,		

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
	DPS567122, DPS567123, DPS561418MAV, DPS561419MAV, DPS567102, DPS567103, DPS567104, DPS567105, DPS567106, DPS567107, DPS567108, DPS567109, DPS567110, DPSHC0002, DPSHC0019, DPSHC0007, DPSHC0008, DPSHC0022, DPSHC0018, DPSHC0029, DPSHC0030, DPSHC0031, DPSHC0037, DPSHC0039, DPSHC0040, DPSHC0041, DPSHC0042 DPSHC0043, DPSHC004, DPSHC0048, DPSHC0049, DPSHC0056, DPSHC0087, DPSHC0070, DPSHC0085, DPSHC0086, DPSHC0013, DPSHC0014, DPSHC0020 from 14119 to 45760 to better align with the SKUs' descriptions. Changed the GMDN Codes for MX822-SCZ, MX823-SCZ and MX821-SCZ from 14119 to 58977 to better align witht he SKUs' descriptions. Changed the GMDN Codes for MX521R-60STCZ and MX521R-70CZ from 14119 to 12170 to better align witht he SKUs' descriptions. Removed MX962Z02STCZ, MX961Y68STCZ, MX961Z02STCZ and MX962Y08STCZ as they're correctly listed on DoC-255. Removed MX257C2CZ as it's correctly listed on DoC-239. Removed DPS564755CZ, DPS566333CZ and SX550181CZ since they are obsolete. Remove DPS620836CZ, MX1570CZ MX858CZ, MX8006CZ, SX540081CZ, SX562504CZ, MX1572CZ, SX580314CZ, DPS721185CZ, SX530136CZ, SX562040CZ, MX4623CZ, SX509748CZ, MX8024ASVCZ, MX8001CZ, MX8004CZ, MX8024ASVLTCZ, SX562285CZ, MX8024RCZ, SX560388CZ, MX8024-ASCZ, SX560981CZ, MX848X2SCP1CZ, MX848CZ and SX580677CZ since they are inactive/post phase out. Added DPS563829CZ from DoC-070 to DoC-069 as all other products with the same IFU (10018442-001) are on DoC-069.		

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126	Changed the GMDN Code for DPS563391 and DPS562003 from 14119 to 45760 to better align with the products' descriptions. Changed the GMDN Code for MX521R-60ST and MX521R-70 from 12170 to 45760 to better align with the SKUs' descriptions. Move MX920NFC2CZ from DoC-070 to DoC-069 as it aligns with products on DoC-069. Didn't remove DPS564960CZ (in Service) despite DVDP1509 rev 110 as DVDP1509 is pending updates which will require DoCs to list Service SKUs. Change the EU Risk Class from IIb to IIa and EU Rule from 10 to 2 for DPS563829CZ as it's not a transducer.	Alicia Wilson	20-SEP-2019
127	Added the following SKUs from DoC-070 as they better fit on this DoC since they are Logical pressure monitoring devices that do not incorporate a Hemodraw system: DPSHC0046, DPSHC0076, DPSHC0081, DPSHC0082, DPSHC0083, DPSHC0084, DPSHC0090, DPSHC0091, DPSHC0092, DPSHC0093, DPSHC0094, MX401G151P1, MX961E181P1, MX961E211P1, MX961G181P1, MX962E181P1, MX962E211P1, MX962G181P1, MX963E181P1, MX963E211P1, MX96AE181P1 and MX96AE211P1. Changed the classification from IIb under rule 10 to Class IIa under rule 2 as they are not active devices. Confirmed by Dominique Neisz.	Alicia Wilson	21-OCT-2019