smiths medical bringing technology to life	**Declaration of Conformity** S1067: Invasive Patient Pressure Monitoring and Accessories Hemo Draw	DoC-070 Revision Number: 113

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):	HemoDraw® blood sampling products LogiCal® pressure transducers NovaTrans® pressure transducers TranStar® pressure transducers
Conformity Assessment Route:	Annex II (excluding Section 4)
Notified Body:	BSI Healthcare Medical Devices 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, USA

Appendix 1: Product List

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
1.	MX4015H002C2	MX4015H002C2CZ	Add On Kit Pole Mounted	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIa	2
2.	SX567010	SX567010CZ	Sma Hemodraw 210cm	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIa	2
3.	MX4015H003C2	MX4015H003C2CZ	Add On Kit Patient Mounted	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIa	2
4.	DPS567015	DPS567015CZ	Sma 2-Fach Mit Hemodraw	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIa	2
5.	DPS567016	DPS567016CZ	Sma Einfach Rot Mit Hemodraw	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIa	2
6.	DPS567013	DPS567013CZ	Sma 3-Fach Rot, Blau, Gelb Mit Hemodraw 210cm	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIa	2
7.	DPS567012	DPS567012CZ	Sma 2 Fach Rot, Blau Mit Hemodraw 210cm	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIa	2
8.	MX9615H002C2	MX9615H002C2CZ	Hemodraw Set Logical Single Line Or/Icu Pole Mount	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIa	2
9.	MX9615H006C2	MX9615H006C2CZ	Hemodraw Set Logical With Anti Shunt Stopcock, Pole Mounted	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIa	2
10.	MX9625H001C2	MX9625H001C2CZ	Hemodraw Double Logical Set Pole Mounted	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIa	2
11.	MX9635H001C2	MX9635H001C2CZ	Hemodraw Triple Logical Set Pole Mounted	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIa	2
12.	MX9515H002C2	MX9515H002C2CZ	Hemodraw Set Transtar Single Line Pole Mounted	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIa	10

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
13.	MX9515H006C2	MX9515H006C2CZ	Hemodraw Set Transtar With Anti Shunt Stopcock, Pole Mounted	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIa	10
14.	MX9525H001C2	MX9525H001C2CZ	Hemodraw Double Transtar Set, Pole Mounted	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIa	10
15.	DPSHC0001	DPSHC0001	1-Fach Logical Anti Shunt Hemodraw	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIa	2
16.	DPSHC0044	DPSHC0044	Logical Hemodraw 1-Fach Druckmess-Set Mit Marvelous	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIa	2
17.	DPSHC0045	DPSHC0045	Logical Hemodraw 2-Fach Druckmess-Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIa	2
18.	MX401H152P1	MX401H152P1	Hemodraw Plus Blood Sampling 152cm Add On Kit -2 Sample Sites	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIb	10
19.	MX951H182P1	MX951H182P1	Transtar 183cm 1-Line Hemodraw Plus Blood Sampling Kit-2 Sample Sites	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIb	10
20.	MX952H182P1	MX952H182P1	Transtar 183cm 2-Line Hemodraw Plus Blood Sampling Kit-2 Sample Sites	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIb	10
21.	MX953H182P1	MX953H182P1	Transtar 183cm 3-Line Hemodraw Plus Blood Sampling Kit-2 Sample Sites	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIb	10
22.	MX95AH182P1	MX95AH182P1	Transtar 183cm 1-Line Hemodraw Plus Blood Sampling Kit Anti Shunt Stopcock-2 Sample Sites	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIb	10
23.	MX961H182P1	MX961H182P1	Logical 183cm 1-Line Hemodraw Plus Blood Sampling Kit-2 Sample Sites	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIb	10
24.	MX961H212P1	MX961H212P1	Logical 213cm 1-Line Hemodraw Plus Blood Sampling Kit-2 Sample Sites	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
25.	MX962H182P1	MX962H182P1	Logical 183cm 2-Line Hemodraw Plus Blood Sampling Kit-2 Sample Sites	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIb	10
26.	MX962H212P1	MX962H212P1	Logical 213cm 2-Line Hemodraw Plus Blood Sampling Kit-2 Sample Sites	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIb	10
27.	MX963H182P1	MX963H182P1	Logical 183cm 3-Line Hemodraw Plus Blood Sampling Kit-2 Sample Sites	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIb	10
28.	MX96AH182P1	MX96AH182P1	Logical 183cm 1-Line Hemodraw Plus Blood Sampling Kit Anti Shunt Stopcock-2 Sample Sites	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIb	10
29.	MX96AH212P1	MX96AH212P1	Logical 213cm 1-Line Hemodraw Plus Blood Sampling Kit With Anti Shunt Stopcock-2 Sample Sites	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIb	10
30.	MX9633	MX9633CZ	Dps Kids Kit (Neonatal) Secure System	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIb	10
31.	MX9636	MX9636CZ	Dps Kids Kit (Pediatric) Secure System	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIb	10
32.	MX9637-LT	MX9637-LTCZ	Dps Kids Kit (Neonatal) Secure System	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIb	10
33.	MX9634	MX9634CZ	Dps Kids Kit (Neonatal) Secure System	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIb	10
34.	DPS564461	DPS564461CZ	Kids Kit (Neonatal) Uni Goettingen	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIb	10
35.	SX566383	SX566383CZ	Neo Hro	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIb	10
36.	MX818	MX818CZ	Bag Reservoir For Blood Sampling/Mon.Kit	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
37.	DPS564137	DPS564137CZ	Kinderdruckmessset	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIb	10
38.	DPS564258	DPS564258CZ	Kids Kit Druckmessung Mit Zvd	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIb	10
39.	DPSHC0096	DPSHC0096	Bonded Hemodraw Plus Double Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIa	10
40.	SX565579	SX565579CZ	Blutentnahme Druckmess Set	Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	45760	IIb	10

Appendix 2: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
07	Updating to current template, updating GMDN and UMDN codes	Breanna Fautsch	19-OCT-2016
08	Updating CE Cert #	Mitchell Madsen	06-APR-2017
009	Change document number format from SXXX to DoC-XXX to load documents into Agile. No updates made to content of this document with the exception of the document number from S1067 to DoC-070 and revision from 08 to 009 and added STED # to header for traceability to STED.	Stacy Novak	31-MAY-2017
010	Added SKUs MX401H152P1, MX951H182P1, MX952H182P1, MX953H182P1, MX95AH182P1, MX961H182P1, MX961H212P1, MX962H182P1, MX962H212P1, MX963H182P1, MX96AH182P1, MX96AH212P1, DPSHC0056 from S1066 as these SKUs below to this Technical File	Mikael Evans	05-JUN-2016
011	Added the following SKUs to this DoC due to incorrect placing of the codes on DoC-069 due to further research on the products from looking at drawings and info on STED fit better with DoC-070: MX9633CZ, MX9636CZ, MX9637-LTCZ, MX961E181P1, MX961G181P1, MX962E181P1, MX962G181P1, MX963E181P1, MX401G151P1, MX96AE211P1, MX961E211P1, MX962E211P1, MX963E211P1, MX9634CZ, DPS564461CZ, SX566383CZ, MX818CZ, DPS563829CZ, DPS564137CZ, MX8036CZ, and DPS564258CZ. Removed SKU DPSHC0056 because the code's drawings and STED info reflected DoC-069 better and moved it to the correct DoC.	Mitchell Madsen	04-OCT-2017
112	Added the following SKU's to this DoC from DoC-069 which were incorrectly added: MX963E211P1, MX96AE181P1, DPSHC0076, DPSHC0081, DPSHC0082, DPSHC0083, DPSHC0084, DPSHC0090, DPSHC0091, DPSHC0092, DPSHC0093, DPSHC0094, DPSHC0096, SX565579CZ Updated Authorized Signatory and transferred DoC content to the current Agile released revision 003 of the DoC template.	Dominique Neisz	17-DEC-2018

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
	Coverage of orphaned EC Certificate referenced on title page is provided by Czech Competent Authority SUKL.		
113	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. Product Tradename was updated to include the following: HemoDraw® blood sampling products, LogiCal® pressure transducers, NovaTrans® pressure transducers, TranStar® pressure transducers. Changed the Notified Body from Intertek AMTAC (0473) to BSI (2797) and the EC Certificate from 1201 09 A CE to CE 669121 as the Notified Body for the SKUs on this DoC has changed from AMTAC to BSI. Changed GMDN Code for all SKUs from 35927 to 45760 to better align with the SKUs' intended use. Moved MX920NFC2CZ and DPS563829CZ to DoC-069 as they better align with the products on DoC-069. Moved DPSHC0046, DPSHC0076, DPSHC0081, DPSHC0082, DPSHC0083, DPSHC0084, DPSHC0090, DPSHC0091, DPSHC0092, DPSHC0093, DPSHC0094, MX401G151P1, MX961E181P1, MX961E211P1, MX961G181P1, MX962E181P1, MX962E211P1, MX962G181P1, MX963E181P1, MX963E211P1, MX96AE181P1 and MX96AE211P1 to DoC-069 as they do not incorporate a Hemodraw system. SKUs DPS721187CZ, DPS721186CZ, MX8036CZ, DPS567004CZ were removed from Appendix 1 due to being in Inactive – Post-Phase Out status in Agile. Formatting and editorial changes to align with FM-DVDP1509-01.105.	Alicia Wilson	21-OCT-2019

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
	An External Reference Number column was added to Appendix 1 table to include the reference number as found on the product label.		