

	Declaration of Conformity	DoC-120 Revision number: 108
	S1162: Medex Infusion Disposables	

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): NU-SITE® capped luer activated valve, HI-FLO™ stop cocks

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: 01 Nov 2019

Name: Stacy Novak

Title: Director, Regulatory Operations

Location of Signatory: Minneapolis, MN USA

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Appendix 1: Product List

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
1.	MX1480	MX1480CZ	FILTER BACTERIA 0.2UM	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	35072	Ila	2
2.	MX1481	MX1481CZ	FILTER BACTERIA 0.2M (PRI MING VOL 0.7ML)	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	35072	Ila	2
3.	MX1482	MX1482CZ	FILTER PARTICLE 1.2M (PR IMING VOL 0.7ML)	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	35072	Ila	2
4.	MX1483	MX1483CZ	FILTER PARTICLE 1.2UM	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	35072	Ila	2
5.	MX1484	MX1484CZ	FILTER NEO 0.2UM POS. CHARGED	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	35072	Ila	2
6.	MX1590-02	MX1590-02CZ	TPN INFUSION SYSTEMS	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	58977	Ila	2
7.	MX1591-01	MX1591-01CZ	PCA DELIVERY SYSTEM	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	58977	Ila	2
8.	MX1591-03	MX1591-03CZ	PCA DELIVERY SYSTEM	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	58977	Ila	2
9.	MX1772M	MX1772MCZ	ADMIN SET WITH DUAL CHECK VALVE	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	58977	Ila	2
10.	MX1789-LR	MX1789-LRCZ	MICROPRIME TUBING W/INJE CT. PORT-ULTRA	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	12170	Ila	2
11.	MX234-1L	MX234-1LCZ	STOPCOCK ULTRA	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	32172	Ila	2
12.	MX448HFB	MX448HFBCZ	NON-DEHP EXT SET 1.2 MICRON FILTER APV=1.0ML	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	35072	Ila	2

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Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
13.	MX448-HL200	MX448-HL200CZ	EXTENSION LINE, LV 200CM, ULTRA	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	12170	Ila	2
14.	MX448-HL20	MX448-HL20CZ	EXTENSION LINE, LV 20CM. ULTRA	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	12170	Ila	2
15.	MX448-HL90	MX448-HL90CZ	EXTENSION LINE, LV 90CM, ULTRA	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	12170	Ila	2
16.	MX453-H2L	MX453-H2LCZ	CONNECTOR T DOUBLE	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	12170	Ila	2
17.	MX453-SL	MX453-SLCZ	CONNECTOR T	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	12170	Ila	2
18.	MX456-F	MX456-FCZ	CONNECTOR Y	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	12170	Ila	2
19.	MX491BP1	MX491BP1CZ	PLUG	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	60538	Ila	2
20.	MX491P1	MX491P1CZ	PLUG	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	60538	Ila	2
21.	MX491-R	MX491-RCZ	PLUG	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	60538	Ila	2
22.	MX492P1	MX492P1CZ	INJECTION SITE.	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	16858	Ila	2
23.	MX493P1	MX493P1CZ	ADAPTOR MLL/MLL	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	60538	Ila	2
24.	MX494P1	MX494P1CZ	ADAPTOR FLL/FLL	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	60538	Ila	2

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Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
25.	MX506-1L	MX506-1LCZ	STOPCOCK	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	32172	Ila	2
26.	MX509002	MX509002CZ	STOPCOCK SINGLE LINE	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	32172	Ila	2
27.	MX534-1LCC	MX534-1LCCCZ	STOPCOCK	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	32172	Ila	2
28.	MX590	MX590CZ	LINE EXTENSION MICROBORE 15CM	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	12170	Ila	2
29.	MX590-LR	MX590-LRCZ	LINE EXTENSION MICROBORE ULTRA 15CM	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	12170	Ila	2
30.	MX591	MX591CZ	LINE EXTENSION MICROBORE 30CM	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	12170	Ila	2
31.	MX592	MX592CZ	LINE EXTENSION MICROBORE 60CM	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	12170	Ila	2
32.	MX593	MX593CZ	LINE EXTENSION MICROBORE 90CM	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	12170	Ila	2
33.	MX594	MX594CZ	LINE EXTENSION MICROBORE 120CM	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	12170	Ila	2
34.	MX595	MX595CZ	LINE EXTENSION MICROBORE 150CM	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	12170	Ila	2
35.	MX595LD	MX595LDCZ	TUBING OPAQUE, LOW VOLUME, 150CM	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	12170	Ila	2
36.	MX595-LR	MX595-LRCZ	LINE EXTENSION MICROBORE 150CM ULTRA	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	12170	Ila	2

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Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
37.	MX597	MX597CZ	LINE EXTENSION MICROBORE 210CM	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	12170	Ila	2
38.	MX611-RV	MX611-RVCZ	CONNECTOR Y WITH CHECK VALVE	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	34099	Ila	2
39.	MX612-HRV	MX612-HRVCZ	CONNECTOR Y, LV, CV, ULTRA	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	34099	Ila	2
40.	MX612-LRRV	MX612-LRRVCZ	Y-CONNECTOR W. CV, ULTRA	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	34099	Ila	2
41.	MX613	MX613CZ	TRIFURCATED MICROPRIME SET	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	12170	Ila	2
42.	MX613-HRV	MX613-HRVCZ	CONNECTOR TRIPLE LV, CV, ULTRA	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	34099	Ila	2
43.	MX616HRV	MX616HRVCZ	QUAD WITH CHECKVALVE, LV, ULTRA	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	34099	Ila	2
44.	MX616-LRRV	MX616-LRRVCZ	QUAD WITH CHECKVALVE	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	34099	Ila	2
45.	MX618	MX618CZ	CONNECTOR TRIPLE W. CHECK VALVE	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	34099	Ila	2
46.	MX618-LR	MX618-LRCZ	MICROPRIME CONNECTOR ULTRA	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	12170	Ila	2
47.	MX743P1	MX743P1CZ	NU-SITE TWO WAY VALVE WITH CAP	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	42750	Ila	2
48.	MX745-01	MX745-01CZ	VALVE DUCKBILL, MINI	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	34099	Ila	2

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Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
49.	MX931-1L	MX931-1LCZ	STOPCOCK HI-FLO	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	32172	Ila	2
50.	MX931Y-1L	MX931Y-1LCZ	HI-FLO STOPCOCK	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	32172	Ila	2
51.	MX934-1L	MX934-1LCZ	STOPCOCK HI-FLO	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	32172	Ila	2
52.	MX934Y-1L	MX934Y-1LCZ	STOPCOCK HI-FLO	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	32172	Ila	2
53.	SM5000P1	SM5000P1CZ	ADAPTOR SMARTSITE	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	34099	Ila	2
54.	SM5003P1	SM5003P1CZ	Y-ADAPTOR WITH SMART SITE	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	34099	Ila	2
55.	SX550244	SX550244CZ	'Y' SET WITH BACK CHECK VALVE	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	34099	Ila	2
56.	SX550390	SX550390CZ	LIPID SET 50/BX	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	12170	Ila	2
57.	SX564455	SX564455CZ	TIVA SET 2001 DEPPE RADKE	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	12170	Ila	2
58.	SX564710	SX564710CZ	TIVA-SET 2001 DEPPE RADKE	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	12170	Ila	2
59.	SX565590	SX565590CZ	TIVA SET KH WALDFRIEDE	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	12170	Ila	2
60.	SX565848	SX565848CZ	TIVA SET	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	12170	Ila	2

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Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
61.	SX600183	SX600183CZ	FEEDING LINE 1.2 MICRON FILTER (BLUE-LIPID) 0.2	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	35072	Ila	2
62.	SX720448	SX720448CZ	TPN INFUSION SET	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	12170	Ila	2
63.	SX720577	SX720577CZ	FILTER KIT	Smiths Medical Czech Republic a.s. Olomoucka 306, 753 01 Hranice, Czech Republic	35072	Ila	2

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Appendix 2: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
005	Updating DoC to the Latest Template, Updating the CE Cert #	Mitchell Madsen	07-MAR-2017
006	Change document number format from SXXX to DoCXXX to load documents into Agile. No updates made to content of this document with the exception of the document number from S1162 to DoC-120 and revision from 005 to 006 and added STED # to header for traceability to STED.	Stacy Novak	05-OCT-2017
107	Changed revision format from "00X" to "1XX" due to update of DVDSOP2005 which requires document revisions to be in the "1XX" format; there are no missing revisions for this DoC (i.e. rev 007 – rev 106). Replaced obsolete GMDN code 37420 with the applicable GMDN codes 58977 and 60538. Replaced obsolete GMDN code 35075 with the applicable GMDN codes 60538 and 46115 due to the obsolescence notification from GMDN Agency. Formatting changes were made to unmerge cells for consistence with the current template, FM-DVDP1509-01 rev. 003. E910CZ has been removed as no data or history can be located for the SKU.	Kendall Lindenman	05-OCT-2018
108	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. Changed the Notified Body from Intertek AMTAC to BSI and the EC Certificate from 1201-01 CE to CE 669121 as the Notified Body for the SKUs on this DoC has changed from AMTAC to BSI. The STED title was revised from "Disposable Infusion Devices" to "Medex Infusion Disposables" to reflect Agile. The GMDN code for the following SKUs were changed to better match the product description: MX743P1CZ was changed from 34099 to 42750; SM5000P1CZ, SM5003P1CZ were changed from 46115 to	Rosanna Lee	30-OCT-2019

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Revision Number	Summary of Changes / Additions	Created / Revised by	Date
	34099; MX453-H2LCZ, MX453-SLCZ, MX456-FCZ, MX613CZ, MX618-LRCZ were changed from 60538 to 12170. Formatting and editorial changes to align with FM-DVDP1509-01.105. An External Reference Number column was added to Appendix 1 table to include external reference number listed on labels.		