

	Declaration of Conformity	DoC-114 Revision Number: 116
	S1143: Needle Safety Devices and Accessories	

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): Needle-Pro® Safety Device
Needle-Pro® EDGE™ Safety Device
Needle-Pro® EDGE™ With Syringe Safety Device

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: 18 OCT 2019

Name: Stacy Novak

Title: Director, Regulatory Operations

Location of Signatory: Minneapolis, MN, USA

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	S1143: Needle Safety Devices and Accessories	

Appendix 1: Product List

Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
1.	401810	HYPO NEEDLE-PRO EDGE 18GX1"	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	59230	Ila	6
2.	401910	HYPO NEEDLE-PRO EDGE 19GX1"	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	59230	Ila	6
3.	402010	HYPO NEEDLE-PRO EDGE 20GX1"	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	59230	Ila	6
4.	402110	HYPO NEEDLE-PRO EDGE 21GX1"	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	59230	Ila	6
5.	402210	HYPODERMIC NEEDLE-PRO EDGE 22GX1"	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	59230	Ila	6
6.	402310	HYPODERMIC NEEDLE-PRO EDGE 23X1"	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	59230	Ila	6
7.	402510	HYPODERMIC NEEDLE-PRO EDGE 25GX1"	Smiths Medical ASD, Inc. 10 Bowman Drive, Keene, New Hampshire 03431 USA	59230	Ila	6
8.	402558	HYPODERMIC NEEDLE-PRO EDGE 25GX5/8 "	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	59230	Ila	6
9.	401815	18GX1.5" EDGE HYPODERMIC NEEDLE-PRO	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	59230	Ila	6
10.	401915	19GX1.5" EDGE HYPODERMIC NEEDLE-PRO	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	59230	Ila	6
11.	402015	20GX1.5" EDGE HYPODERMIC NEEDLE-PRO	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	59230	Ila	6
12.	402115	21GX1.5" EDGE HYPODERMIC NEEDLE-PRO	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	59230	Ila	6

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	S1143: Needle Safety Devices and Accessories	

Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
13.	402215	22GX1.5" EDGE HYPODERMIC NEEDLE-PRO	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	59230	Ila	6
14.	402315	23GX1.5" EDGE HYPODERMIC NEEDLE-PRO	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	59230	Ila	6
15.	402515	25GX1.5" EDGE HYPODERMIC NEEDLE-PRO	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	59230	Ila	6
16.	402605	26GX0.5"EDGE HYPODERMIC NEEDLE-PRO	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	59230	Ila	6
17.	402705	27GX0.5"EDGE HYPODERMIC NEEDLE-PRO	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	59230	Ila	6
18.	403005	30GX0.5" EDGE HYPODERMIC NEEDLE-PRO	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	59230	Ila	6
19.	4027125	27GX1.25" EDGE HYPODERMIC NEEDLE-PRO	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	59230	Ila	6
20.	412558	NEEDLE-PRO EDGE TB 25GX5/8 WITH SYRINGE 1ML LL	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	45042	Ila	6
21.	412705	NEEDLE-PRO EDGE TB 27GX1/2 WITH SYRINGE 1ML LL	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	45042	Ila	6
22.	4317	HYPO NEDL-PRO EDGE/SY 1ML INSULIN U-100 26X1/2	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	38501	Ila	6
23.	4319	HYPO NEDL-PRO EDGE/SY 1ML INSULIN U-100 27X1/2	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	38501	Ila	6
24.	431810	18GX1" EDGE NEEDLE W/3ML LL SYRINGE	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	45042	Ila	6

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	S1143: Needle Safety Devices and Accessories	

Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
25.	431815	18GX1.5" EDGE NEEDLE W/3ML LL SYRINGE	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	45042	Ila	6
26.	431910	19GX1" EDGE NEEDLE W/3ML LL SYRINGE	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	45042	Ila	6
27.	431915	19GX1.5" EDGE NEEDLE W/3ML LL SYRINGE	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	45042	Ila	6
28.	432010	20GX1" EDGE NEEDLE W/3ML LL SYRINGE	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	45042	Ila	6
29.	432015	20GX1.5" EDGE NEEDLE W/3ML LL SYRINGE	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	45042	Ila	6
30.	432110	21GX1" EDGE NEEDLE W/3ML LL SYRINGE	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	45042	Ila	6
31.	432115	21GX1.5" EDGE NEEDLE W/3ML LL SYRINGE	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	45042	Ila	6
32.	432210	NEEDLE PRO EDGE 22GX1" WITH SYRINGE 3ML	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	45042	Ila	6
33.	432215	22GX1.5" EDGE NEEDLE W/3ML LL SYRINGE	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	45042	Ila	6
34.	432310	NEEDLE PRO EDGE 23GX1" WITH SYRINGE 3ML	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	45042	Ila	6
35.	432510	NEEDLE PRO EDGE 25GX1" WITH SYRINGE 3ML	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	45042	Ila	6
36.	432558	NEEDLE PRO EDGE 25GX5/8" WITH SYRINGE 3ML	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	45042	Ila	6

	Declaration of Conformity	DoC-114 Revision Number: 116
	S1143: Needle Safety Devices and Accessories	

Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
37.	452010	20G X 1" NEEDLE-PRO EDGE SAFETY DEVICE WITH 5ML LL SYRINGE	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	45042	Ila	6
38.	452015	20G X 1 1/2" NEEDLE-PRO EDGE SAFETY DEVICE WITH 5 ML LL SYRINGE	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	45042	Ila	6
39.	452110	21G X 1" NEEDLE-PRO EDGE SAFETY DEVICE WITH 5 ML LL SYRINGE	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	45042	Ila	6
40.	452115	21G X 1 1/2" NEEDLE-PRO EDGE SAFETY DEVICE WITH 5ML LL SYRINGE	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	45042	Ila	6
41.	452215	22G X 1 1/2" NEEDLE-PRO EDGE SAFETY DEVICE WITH 5 ML LL SYRINGE	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	45042	Ila	6
42.	4102010	20G X 1" NEEDLE-PRO EDGE SAFETY DEVICE WITH 10 ML LL SYRINGE	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	45042	Ila	6
43.	4102015	20G X 1 1/2" NEEDLE-PRO EDGE SAFETY DEVICE WITH 10 ML LL SYRINGE	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	45042	Ila	6
44.	4102115	21G X 1 1/2" NEEDLE-PRO EDGE SAFETY DEVICE WITH 10 ML LL SYRINGE	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	45042	Ila	6
45.	4428-1	HYPO NEEDLE-PRO FOR INSULIN 28GX1/2" 1CC	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	38501	Ila	6
46.	4429-1	HYPO NEEDLE-PRO FOR INSULIN 29GX1/2" 1CC	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	38501	Ila	6
47.	4428-5	HYPO NEEDLE-PRO FOR INSULIN 28GX1/2" .5CC	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	38501	Ila	6
48.	4429-5	HYPO NEEDLE-PRO FOR INSULIN 29GX1/2" .5CC	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	38501	Ila	6

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	S1143: Needle Safety Devices and Accessories	

Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
49.	4430-5	HYPO NEEDLE-PRO FOR INSULIN 30G X 1/2" 0.5CC	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	38501	Ila	6
50.	4429-3	HYPO NEEDLE-PRO FOR INSULIN 29GX1/2" .3CC	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	38501	Ila	6
51.	4430-3	HYPO NEEDLE-PRO FOR INSULIN 30G X1/2" 0.3CC	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	38501	Ila	6
52.	4425-TB	HYPO NEEDLE-PRO FOR TB 25GX5/8" 1CC	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	45042	Ila	6
53.	4426-TB	HYPO NEEDLE-PRO FOR TB 26GX3/8" 1CC	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	45042	Ila	6
54.	4427-TB	HYPO NEEDLE-PRO FOR TB 27GX1/2" 1CC	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	45042	Ila	6
55.	4310	HYPO NEDL-PRO EDGE SY1ML 25X5/8	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	45042	Ila	6
56.	4312	HYPO NEDL-PRO EDGE SY1ML 26X1/2	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	45042	Ila	6

	Declaration of Conformity	DoC-114 Revision Number: 116
	S1143: Needle Safety Devices and Accessories	

Appendix 2: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
013	Updated to new template, added EC Cert information; changed document number format from SXXX to DoC-XXX to load documents into Agile; changed DoC number from S1006 to DoC-015 and revision from 012 to 013 and added STED # to header for traceability to STED; removed all SKUs applicable to Arterial Blood Gas devices as they are now covered under STED #1133 and those applicable to the Saf-T Wing and Saf-T Holder as they are now covered under STED #1138; removed obsolete SKUs. Removed Notified Body address for consistency across all DoCs.	Stacy Novak	02-JUN-2017
014	The purpose of this revision update was in response to Notified Body Transfer. The changes to this DoC include: Notified Body name and number from Intertek 0473 to BSI 0086, the certificate number from 091-01 A CE to CE660824, the revision from 013 to 014, updated the Group on EU Cert from Needle Safety Devices and Accessories to Hypodermic Needle Safety align with name of group on the EC certificate and removed the SKU 4313 as it is Obsolete. No other updates were made.	Brent Pearson	11-OCT-2017
115	Updated the DoC to the latest template in Agile from Revision 002 to 003. Changed the Authorized Signatory from Stacy Novak to Sunita Teekasingh. Updated the Product Descriptions for the product codes in Appendix 1 to match their labels. Replaced obsolete GMDN Code 12745 with the applicable GMDN 59230 due to obsolescence notification from GMDN Agency. Made formatting changes to Appendix 1 such as unmerging cells and filling in the information of the empty cells. Changed revision format from "00X" to "1XX" due to update of DVSOP2005 which requires document revisions to be in the "1XX" format; there are no missing revisions for this DoC (i.e. rev 015-rev 114).	Mitchell Madsen	12-OCT-2018
116	- Changed the legal manufacturer from MKEE to MMSP as per FM-DVSOP8005-05.	Mitchell Madsen	15-OCT-2019

	Declaration of Conformity	DoC-114 Revision Number: 116
	S1143: Needle Safety Devices and Accessories	

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
	-Changed the EU Representative from the Ashford, UK facility to the Hranice, Czech Republic facility. An EU Representative is needed if a product is commercially distributed in the EU and not manufactured in the EU. Since Ashford will no longer be part of the EU, due to Brexit, the EU Representative was changed from the Ashford facility to the Hranice facility. -Changed the Notified Body from BSI UK (0086) to BSI NL (2797) as BSI is migrating issued certificates from the UK to the Netherlands due to Brexit. The EC Certificate was updated from CE 660824 to CE 669121. -Changed the Product Descriptions for the Catalog Numbers in Appendix 1 to match their Agile Descriptions -Updated the Keene address in the Manufacturing Site column in Appendix 1 to match the EC Certificate, CE 669121. - GMDN Code was updated to better match the product description and intended use for the following SKUs: 412558, 412705, 431810, 431815, 431910, 431915, 432010, 432015, 432110, 432115, 432210, 432215, 432310, 432510, 432558, 452010, 452015, 452110, 452115, 452215, 4102010, 4102015, 4102115, 4310, 4312 from 35904 to 45042; 4317, 4319 from 35904 to 38501; 4425-TB, 4426-TB, 4427-TB from 38501 to 45042. - Formatting and editorial changes to align with FM-DVDP1509-01.105.		