smiths medical bringing technology to life	**Declaration of Conformity** S1138: Blood Sampling Devices and Accessories; MPS Blood Collection Products	DoC-110 Revision Number: 117

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 - Mesto, 753 01 Hranice, Czech Republic
Product Tradename(s):	Saf-T Holder® blood tube holder Saf-T Wing® blood collection set Saf-T Wing® detached blood collection sets
Conformity Assessment Route:	Annex II (excluding Section 4), General IVD
Notified Body:	BSI Healthcare Medical Devices Certification Notified Body #2797 NA for IVD products
EC Certificate Number:	CE 669121, NA for IVD products

Smiths Medical ASD, Inc. hereby declares under its sole responsibility that the product(s) referenced in Product List (1) 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.

Smiths Medical ASD, Inc. hereby declares under its sole responsibility that the product(s) referenced in Product List (2) conform to the relevant provisions of EU Council Directive 98/79/EC concerning In Vitro Diagnostic Medical Devices as transposed into national regulations and by subsequent Directives, laws, and other national regulations.

Authorized Signatory:

Signature: Stacy Novak Date: 10 Jan 2020

Name: Stacy Novak

Title: Director, Regulatory Operations

Location of Signatory: Minneapolis, MN, 55442

Appendix 1: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
014	The purpose of this revision update was in response to Notified Body Transfer. The changes to this DoC include: Transferred content to FM-DVDP1509-01 revision 002 template; Updated Notified Body name and number from Intertek 0473 to BSI 0086; Updated EC cert information from 091-01 A CE to CE660824; Change document number format from SXXX to DoC XXX to load documents into Agile from S1138 to DoC-110; Added STED # to header for traceability to STED, renumbered items in Appendix 1 to align with updated template and revision from 013 to 014. No other updates were made to the content of this document.	Brent Pearson	10-OCT-2017
115	STED name was changed from “Saf-T Blood Collection” to “Blood Sampling Devices and Accessories; MPS Blood Collection Products” to match the STED description in Agile. Changed the legal manufacturer from MKEE to MMSP 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 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 number was updated from CE 660824 to CE 669121. Product Descriptions in Appendix 1 were updated for the all SKUs to match the product description in Agile. Manufacturing Sites in Appendix 1 were updated to match the address as listed on CE 669121. Manufacturing Site in Appendix 1 for the following SKUs were updated to match the manufacturing site listed in Agile: SKU	Rosanna Lee	28-OCT-2019

	96007 was updated from Smiths Medical's Keene facility to Innovation Medical Manufacturing Company; 96009 was updated from Smiths Medical's Keene facility to SMC. Confirmed by Jeffrey Langdell. GMDN Code in Appendix 1 was updated to better match the product description and intended use for the following SKUs: 96000, 96000S, 96002, 96002S, 96004, 96005 from 37566 to 58284; 982106 from 37566 to 58497; 982106D, 982106L, 982112L, 982306D, 982306L, 982312L, 982506L, 982512L from 35209 to 58497; 972106, 972112, 972306, 972312, 972506 and 972512 from 35209 to 58490. Formatting and editorial changes to align with FM-DVDP1509-01.105. Document revision number reassigned from 0xx to 1xx to align with DVSOP2005.		
116	DoC Template updated from revision 105 of FM-DVDP1509-01 to revision 106. The following SKU's were identified as General IVD products: 96000, 96000S, 96002, 96002S, 96004, 96005, 96007, 96009 They have been moved to the newly created "Product List (2)" of the attached SKU reference page. Their associated risk classification has been denoted as "General IVD" with no applicable rule. Corrected the GMDN term for the following SKU's: 96000, 96000S, 96002, 96002S, 96004, 96005 from 58284 to 37566 as none of them contain a pre-attached needle. Title block of DoC has been modified to address the In Vitro Diagnostic Medical Devices Directive.	Dominique Neisz	20-DEC-2019
117	Administrative correction to DoC number in header of document. Corrected from DoC-115 to DoC-110	Dominique Neisz	10-JAN-2020

Catalog Number	Product Description	GMDN Code	EU Risk Class	EU Rule
972106	SAF-T WING 21G X 3/4'	58490	IIa	6
972112	SAF-T WING 21G X 3/4'	58490	IIa	6
972306	SAF-T WING 23G X 3/4'	58490	IIa	6
972312	SAF-T WING 23G X 3/4'	58490	IIa	6
972506	SAF-T WING 25G X 3/4'	58490	IIa	6
972512	SAF-T WING 25G X 3/4'	58490	IIa	6
982106	SAF-T WING 21G X 3/4'	58497	IIa	6
982106D	SAF-T WING 21G X 3/4'	58497	IIa	6
982106L	SAF-T WING 21G X 3/4'	58497	IIa	6
982112	SAF-T WING 21G X 3/4'	58497	IIa	6
982112D	SAF-T WING 21G X 3/4'	58497	IIa	6
982112L	SAF-T WING 21G X 3/4'	58497	IIa	6
982306	SAF-T WING 23G X 3/4'	58497	IIa	6
982306D	SAF-T WING 23G X 3/4'	58497	IIa	6
982306L	SAF-T WING 23G X 3/4'	58497	IIa	6
982312	SAF-T WING 23G X 3/4'	58497	IIa	6
982312D	SAF-T WING 23G X 3/4'	58497	IIa	6
982312L	SAF-T WING 23G X 3/4'	58497	IIa	6
982506	SAF-T WING 25G X 3/4'	58497	IIa	6
982506D	SAF-T WING 25G X 3/4'	58497	IIa	6
982506L	SAF-T WING 25G X 3/4'	58497	IIa	6
982512	SAF-T WING 25G X 3/4'	58497	IIa	6
982512D	SAF-T WING 25G X 3/4'	58497	IIa	6
982512L	SAF-T WING 25G X 3/4'	58497	IIa	6

Catalog Number	Product Description	GMDN Code	EU Risk Class	EU Rule
96000	SAF-T HOLDER W/LUER ADAPTER + 200/CA	37566	General IVD	N/A
96000S	SHORT SAF-T HOLDER W/MALE LUER ADAPTER + 200/CA	37566	General IVD	N/A
96002	SAF-T HOLDER W/FEMALE LUER ADAPTER + 200/CA	37566	General IVD	N/A
96002S	SHORT SAF-T HOLDER W/FEMALE LUER ADAPTER + 200/CA	37566	General IVD	N/A
96004	SAF-T HOLDER BLOOD CULTURE W/MALE LUER + 50/CA	37566	General IVD	N/A
96005	SAF-T HOLDER BLOOD CULTURE W/FEMALE LUER + 50/CA	37566	General IVD	N/A
96007	PEDIATRIC TUBE INSERT NS + 100/CA	37566	General IVD	N/A
96009	SINGLE USE BLOOD COLLECTION HOLDER 1000/CA	37566	General IVD	N/A