smiths medical bringing technology to life	**Declaration of Conformity** S1155: Deltec Port-A-Cath Implantable Access System	DoC-118 Revision Number: 112

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):	PORT-A-CATH® Implantable Venous Access System, PORT-A-CATH® II Implantable Venous Access System, PORT-A-CATH® POWER P.A.C. Implantable Venous Access System (capacity for use with power injection), PORT-A-CATH® II POWER P.A.C. Implantable Venous Access System (capacity for use with power injection), and ProPort® Implantable Venous Access System
Conformity Assessment Route:	Annex II (Section 4)
Notified Body:	BSI Healthcare Medical Devices Certification Notified Body #2797
EC Certificate Number:	CE 669193 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.

Reference Attachment 1 for list of affected SKUs.

Authorized Signatory:

Signature: Adam Johnson Date: 27-OCT-2020

Name: Adam Johnson

Title: Global Quality Regulatory Affairs Project Manager

Location of Signatory: Minneapolis, MN, US

Appendix 1: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
112	Added EC Certificate reference CE 669121	Ashley Levang	26-OCT-2020
111	Updated template from 105 to 107 which included transferring the SKUs into an excel spreadsheet as Attachment 1. Updated 'Product Description' for all SKUs to align with DE certificate and product labeling. This will prevent potential future issues during international registration activity and product shipments.	Ashley Levang	29-JUL-2020
110	-Updated template from 003 to 105. -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 number remains the same. -Added "ProPort® implantable venous access system" to Tradename(s) field to reflect SKUs 21-4150-24, 21-4151-24, 21-4152-24, 21-4153-24, 21-4154-24, 21-4155-24, 21-4165-24, 21-4170-24, 21-4171-24, 21-4172-24, 21-4173-24, 21-4182-24, 21-4183-24, 21-4186-24 and 21-4187-24 -Revised product descriptions to match descriptions listed on EC Certificate 669193. -Removed SKUs 21-8070-24 and 21-2000-24 as they're inactive/post-phout. -Changed GMDN Code from 35911 to 61493 for SKUs 21-1500-22 and 21-1501-22 as 35911 has been obsoleted by the GMDN Agency. 61493 is the best fit code.	Alicia Wilson	19-FEB-2020

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
	-Changed GMDN Code from 35911 to 61494 for the following SKUs as 35911 has been obsoleted by the GMDN Agency and 61494 is the best fit code: 21-4000-24, 21-4003-24, 21-4008-24, 21-4009-24, 21-4022-24, 21-4023-24, 21-4024-24, 21-4025-24, 21-4034-24, 21-4035-24, 21-4036-24, 21-4037-24, 21-4050-24, 21-4051-24, 21-4052-24, 21-4053-24, 21-4054-24, 21-4055-24, 21-4063-24, 21-4065-24, 21-4066-24, 21-4067-24, 21-4068-24, 21-4069-24, 21-4070-24, 21-4071-24, 21-4073-24, 21-4082-24, 21-4083-24, 21-4084-24, 21-4085-24, 21-4150-24, 21-4151-24, 21-4152-24, 21-4153-24, 21-4154-24, 21-4155-24, 21-4165-24, 21-4170-24, 21-4171-24, 21-4172-24, 21-4173-24, 21-4182-24, 21-4183-24, 21-4186-24, 21-4187-24, 21-4572-24, 21-4573-24, 21-4590-24, 21-4591-24, 21-8066-24, 21-8068-24, 21-4422-24, 21-4423-24, 21-4424-24, 21-4425-24, 21-4436-24, 21-4437-24, 21-4452-24, 21-4453-24, 21-4454-24, 21-4455-24, 21-4463-24, 21-4465-24, 21-4470-24, 21-4471-24, 21-4473-24, 21-4474-24, 21-4475-24, 21-4476-24, 21-4477-24, 21-4482-24, 21-4483-24, 21-4485-24, 21-4872-24, 21-4873-24, 21-8466-24, 21-8468-24, 21-8469-24 and 21-8470-24		
009	Code 21-2000-24 was removed in Revision 008 as it was Inactive in Agile. However, due to the fact that the code is “Phase Out” in Oracle and commercial distribution can continue, this code is being added back onto the DoC until inventory is depleted. Updated DoC to the latest Template in Agile.	Mitchell Madsen	21-NOV-2017
008	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 and the certificate number from 058.1 -05 DE to CE 669193. Additional changes include: Annex, and Authorized Signatory, changed document number format from SXXX to DoCXXX (from S1155 to DoC-118) to load documents into Agile, removed product codes # 21-2000-24, 21-0501-22, 21-3000-24, 21-4004-24, 21-4010-24, 21-4140-22, 21-4160-24,	Brent Pearson	17-AUG-2017

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
	21-4161-24, 21-4162-24, 21-4163-24, 21-4164-24, 21-4184-24, 21-4185-24, 21-4188-24, 21-4189-24, 21-4653-24, 21-4655-24, 21-4672-24, 21-4673-24, 21-4683-24, 21-4685-25, 21-4690-24, 21-4691-24, 21-4953-24, 21-4955-24, 21-4972-24, 21-4973-24, 21-4983-24, 21-4985-24, 21-8010-24, 21-8011-24, 21-8050-24, 21-8052-24, 21-8053,24, 21-8065-24, 21-8067-24, 21-8069-24, 21-8465-24, 21-8652-24 and 21-8662-24 as these codes are either obsolete or inactive and can no longer be commercially distributed, renumbered the products on Appendix 1 accordingly and updated the document revision from 007 to 008 and added STED # to header for traceability to STED.		