

	Declaration of Conformity	DoC-010 Revision Number: 108
	S1001: Breathing Systems: Adaptors and Connectors	

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): Portex®

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: 12 Sep 2019

Name: Stacy Novak

Title: Sr. Manager, Regulatory Operations

Location of Signatory: Minneapolis, MN USA

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Appendix 1: Product List

Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
1.	100/250/001	Swivel Connector Reusable 15mm	Smiths Healthcare Manufacturing SA de CV Avenida Calidad No.4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	61347	Ila	2
2.	100/251/001	Catheter Mount Adaptor - Female 15mm Non-Sterile	Smiths Healthcare Manufacturing SA de CV Avenida Calidad No.4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	42476	Ila	2
3.	100/255/150	Connector Double Swivel	Smiths Healthcare Manufacturing SA de CV Carretera Miguel Alemán Km 21.7, Parque Industrial Monterrey, Apodaca NL CP 66603 Mexico	61347	Ila	2
4.	100/257/000	Connector-Fibreoptic Bron Swiv	Smiths Healthcare Manufacturing SA de CV Avenida Calidad No.4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	61347	Ila	2
5.	100/590/000	Catheter Mount 15mm & 22mm Female Terminations	Smiths Healthcare Manufacturing SA de CV Carretera Miguel Alemán Km 21.7, Parque Industrial Monterrey, Apodaca NL CP 66603 Mexico	42476	Ila	2
6.	100/594/000	Catheter Mount Double Swivel Connector	Smiths Healthcare Manufacturing SA de CV Carretera Miguel Alemán Km 21.7, Parque Industrial Monterrey, Apodaca NL CP 66603 Mexico	42476	Ila	2
7.	225-3507-800	Elbow Standard Clr Ns	Smiths Healthcare Manufacturing SA de CV Avenida Calidad No.4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	61346	Ila	2

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Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
8.	225-3523-804	Elbow Gs Capped Pt Clr Ns	Smiths Healthcare Manufacturing SA de CV Avenida Calidad No.4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	61346	Ila	2
9.	225-3524-804	Straight Conn, Gas Sampling Capped Port, Clear	Smiths Healthcare Manufacturing SA de CV Avenida Calidad No.4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	61346	Ila	2

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Appendix 2: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
003	Remove codes 60-0010* 60-1502* & 60-1510* these are on S1098 Change to the correct certificate number	Kay Friend	02-MAY-2017
004	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 S1001 to DoC-010 and revision from 003 to 004 and added STED # to header for traceability to STED.	Stacy Novak	31MAY2017
005	The purpose of this revision update was in response to Notified Body Transfer. The Changes to this DoC include: Notified Body name from Intertek to BSI, updated to new certificate number and updated to new revision from 004 to 005	Manasa Boppana	13-July-2017
106	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 005-rev 106). Replaced obsolete GMDN 34838 with the applicable GMDN 61346 and 61347 due to obsolescence notification from GMDN Agency. Formatting changes were made to unmerge cells for consistence with the current template, FM-DVDP1509-01 rev. 003. Description updates made to resemble current product labels.	Kendall Lindeman	16-OCT-2018
107	-Updated the DoC to the latest template from Rev 003 to 105 -Changed the STED Name on the DoC from "Breathing Systems – Adaptors & Connectors" to "Breathing Systems: Adaptors and Connectors" to match the STED Name in Agile	Mitchell Madsen	27-AUG-2019

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Revision Number	Summary of Changes / Additions	Created / Revised by	Date
	-Changed the legal manufacturer from MHYT 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 BSI UK (0086) to BSI NL (2797) as BSI is migrating issued certificates from the UK to the Netherlands due to Brexit. Changed the EC Certificate from "CE 661325" to "CE 669121" due to the Legal Manufacturer change. -Changed the Authorized Signatory from Donna Semlak to Stacy Novak -Updated the Product Descriptions for Catalog Numbers in Appendix 1 to match the descriptions in Agile. -Changed the Manufacturing Site from Tijuana to Monterrey for the following SKUs to match the information in Agile: 100/255/150, 100/590/000, 100/594/000 -Revised the Tijuana and Monterrey Manufacturing Site addresses to match the addresses listed on EC Certificate 669121. -Updated the GMDN Code for 100/251/001 from 61346 to 42476 to better align with the SKU's descriptions. -Updated the GMDN Code for 100/257/000 from 42601 to 61347 to better align with the SKU's descriptions. -Updated the GMDN Code for 100/590/000 and 100/594/000 from 61347 to 42476 to better align with the SKU's descriptions.		
108	Changed GMDN Code for 100/250/001 from 42601 to 61347 to better align with the product's description and intended use.	Alicia Wilson	13-SEP-2019