

	Declaration of Conformity	DoC-045 Revision number: 106
	S1039 Portex Oxygen and Humidity Management - HMEs	

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): Portex® Thermovent®

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: Angela Kilian

Date: 16-Oct-2019

Name: Angela Kilian

Title: Director, Regulatory Affairs

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	EU Risk Class	EU Rule
1.	002841	N/A	Heat & Moisture Exchanger Flex Tube	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No.4, Industrial Internacional Tijuana, Tijuana, B.C C.P. 22425 Mexico	35530	Ila	2
2.	002841P	N/A	Heat & Moisture Exchanger with Gas Port And Flex Tube	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No.4, Industrial Internacional Tijuana, Tijuana, B.C C.P. 22425 Mexico	35530	Ila	2
3.	002850P	N/A	Heat & Moisture Exchanger Filtered, Gas Port, Cap	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No.4, Industrial Internacional Tijuana, Tijuana, B.C C.P. 22425 Mexico	35530	Ila	2
4.	002851P	N/A	Heat & Moisture Exchanger Filt, Gas Port, Cap, Flex Tube	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No.4, Industrial Internacional Tijuana, Tijuana, B.C C.P. 22425 Mexico	35530	Ila	2
5.	002865	N/A	Filtered HME, Heat & Passive Humidification Filter Circuit	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No.4, Industrial Internacional Tijuana, Tijuana, B.C C.P. 22425 Mexico	35530	Ila	2
6.	002866	N/A	HME FIL FLX TU NS	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No.4, Industrial Internacional Tijuana, Tijuana, B.C C.P. 22425 Mexico	35530	Ila	2

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Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	GMDN	EU Risk Class	EU Rule
7.	100/570/015	100/570/015CZ	Thermovent T - 15mm Connector Heat & Moisture Exchanger	Smiths Medical Czech Republic a.s. Olomoucka 306 753 01 Hranice, Czech Republic	35530	Ila	2
8.	100/570/022	N/A	Thermovent T2 Sterile	Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman Km 21.7, Parque Industrial Monterrey, Apodaca NL CP 66603 Mexico	35530	Ila	2
9.	100/580/015	N/A	Thermovent 600-15mm/22mm Conn Heat & Moisture Exchanger	Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman Km 21.7, Parque Industrial Monterrey, Apodaca NL CP 66603 Mexico	35530	Ila	2
10.	100/582/000	N/A	Thermovent 1200-15mm/22mm Conn HME	Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman Km 21.7, Parque Industrial Monterrey, Apodaca NL CP 66603 Mexico	35530	Ila	2
11.	100/585/000	N/A	Thermovent Hepa, Heat/Moisture Exchanger Filter	Pentair Filtration Solutions 1350 Hammond Road St. Paul Minnesota 55110 USA	35530	Ila	2
12.	100/585/000N	N/A	Thermovent Hepa Filtered HME W/GSP NS	Pentair Filtration Solutions 1350 Hammond Road St. Paul Minnesota 55110 USA	35530	Ila	2
13.	100/585/000T	N/A	Thermovent Hepa, Heat Moisture Exchange Filter W/GSP & Tethered Cap	Pentair Filtration Solutions 1350 Hammond Road St. Paul Minnesota 55110 USA	35530	Ila	2

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Appendix 2: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
004	Updating the DoC to the latest Template	Mitchell Madsen	15-DEC-2016
005	Update the manufacturing site for 100/570/015 to MMON. Add Thermovent with Tethered Cap SKU to DoC. Changed 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 S1039 to DoC-045 and revision from 004 to 005 added STED # to header for traceability to STED, updated the effective date, updated notified body from Intertek to BSI, updated the cert number 053 01 A CE to CE661325, edited the Conformity Assessment and removed SKU's 002840 and 002840P as they are inactive.	Manasa Boppana	05-SEP-2017
106	Changed the template from rev 002 to rev 105. Changed the DoC revision from 005 to 106 per DVSOP2005 revision formatting requirements. Changed formatting by unmerging cells in Appendix 1 for easier editing and reading. Changed STED title from "Oxygen and Humidity Management" to "Portex Oxygen and Humidity Management – HMEs" to match the STED's title in Agile. Added "Portex® Thermovent®" as the Product Tradename as it's the tradename for the affected SKUs. 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.	Alicia Wilson	14-OCT-2019

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Revision Number	Summary of Changes / Additions	Created / Revised by	Date
	Revised Tijuana and Monterrey's Manufacturing Site addresses to match addresses listed on EC Certificate 669121. Changed the Manufacturing Site for 100/570/015 from Monterrey to Hranice to reflect what's listed in Agile and Oracle. Changed Product Descriptions to match the descriptions in Agile. Split the "Catalog Number" column into two: External Reference Number and Internal Reference Number to reflect the CZ code for 100/570/015.		