

	Declaration of Conformity	DoC-083 Revision number: 108
	S1096: Bronchial Hygiene Devices	

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® acapella® choice vibratory PEP therapy system
Portex® acapella® duet respiratory therapy system with nebulizer

Conformity Assessment Route: Annex II (excluding Section 4)

Notified Body: TUV SUD Product Service GmbH
Zertifizierstellen
Ridlerstraße 65
80339 MÜNCHEN
Germany
Notified Body #0123

EC Certificate Number: G1 17 04 97063 001

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: _____

01 Nov 2019

Name: Stacy Novak

Title: Director, Regulatory Operations

Location: 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.	21-1531	ACAPELLA DH GREEN MOUTHPIECE, UNIT CARTON NS	Smiths Medical ASD Inc. 6250 Shier Rings Road, Dublin, Ohio 43016 USA	43947	Ila	5
2.	21-1016	ACAPELLA DM BLUE MOUTHPIECE, UNIT CARTON NS	Smiths Medical ASD Inc. 6250 Shier Rings Road, Dublin, Ohio 43016 USA	43947	Ila	5
3.	27-9002	ACAPELLA DUET WITH MOUTHPIECE NS, UNIT CARTON	Smiths Medical ASD Inc. 6250 Shier Rings Road, Dublin, Ohio 43016 USA	43947	Ila	5
4.	27-7001	ACAPELLA CHOICE NS, UNIT CARTON	Smiths Medical ASD Inc. 6250 Shier Rings Road, Dublin, Ohio 43016 USA	43947	Ila	5
5.	27-7000	ACAPELLA CHOICE NS	Smiths Medical ASD Inc. 6250 Shier Rings Road, Dublin, Ohio 43016 USA	43947	Ila	5
6.	27-9000	ACAPELLA DUET NS	Smiths Medical ASD Inc. 6250 Shier Rings Road, Dublin, Ohio 43016 USA	43947	Ila	5
7.	27-9001	ACAPELLA DUET NO SVN/FT NS	Smiths Medical ASD Inc. 6250 Shier Rings Road, Dublin, Ohio 43016 USA	43947	Ila	5
8.	21-1015	ACAPELLA DM BLUE MOUTHPIECE NS	Smiths Medical ASD Inc. 6250 Shier Rings Road, Dublin, Ohio 43016 USA	43947	Ila	5
9.	21-1530	ACAPELLA DH GREEN MOUTHPIECE NS	Smiths Medical ASD Inc. 6250 Shier Rings Road, Dublin, Ohio 43016 USA	43947	Ila	5
10.	21-3015	ACAPELLA DM BLUE W/ PEDIATRIC MASK NS	Smiths Medical ASD Inc. 6250 Shier Rings Road, Dublin, Ohio 43016 USA	43947	Ila	2
11.	21-3530	ACAPELLA DH GREEN W/ PEDIATRIC MASK NS	Smiths Medical ASD Inc. 6250 Shier Rings Road, Dublin, Ohio 43016 USA	43947	Ila	2
12.	21-5015	ACAPELLA DM BLUE W/ MEDIUM MASK NS	Smiths Medical ASD Inc. 6250 Shier Rings Road, Dublin, Ohio 43016 USA	43947	Ila	2

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Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
13.	21-5530	ACAPELLA DH GREEN W/ MEDIUM MASK NS	Smiths Medical ASD Inc. 6250 Shier Rings Road, Dublin, Ohio 43016 USA	43947	Ila	2
14.	21-7015	ACAPELLA DM BLUE W/ LARGE MASK NS	Smiths Medical ASD Inc. 6250 Shier Rings Road, Dublin, Ohio 43016 USA	43947	Ila	2
15.	21-7530	ACAPELLA DH GREEN W/ LARGE MASK NS	Smiths Medical ASD Inc. 6250 Shier Rings Road, Dublin, Ohio 43016 USA	43947	Ila	2
16.	27-0050	ACAPELLA CHOICE MOUTHPIECE NS	Smiths Medical ASD Inc. 6250 Shier Rings Road, Dublin, Ohio 43016 USA	43947	Ila	5

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Appendix 2: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
03	Update notified body certificate section, updated to latest DoC template revision, split DoC's into Keene and St. Paul documents per Sr. Manager request	Breanna Fautsch	07-NOV-16
04	Update the EC Cert product family from "Bronchial Hygiene" to "Vibratory Positive Expiratory Device"	Mitchell Madsen	01-DEC-16
005	Update EC Cert Reference and Legal Manufacturer address. Change number to S1096-1 for MMSP codes.	Amanda Haider	03-MAY-2017
006	Change 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 S1096 to DoC-083 and revision from 005 to 006 and added STED # to header for traceability to STED.	Callie Frick	05-JUN-2017
007	Updated to next revision, changed the effective date, changed the Authorized Signatory, and removed the SKU's 55-4033, 55-4045, 55-4060, and 55-4090 and added to DoC-183 as they are class I/II and are self-certified.	Manasa Boppana	03-OCT-2017
108	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. STED title was revised from "Bronchial Hygiene and Lung Expansion" to "Bronchial Hygiene Devices" to match Agile. Notified Body TUV SUD Product Service GmbH address was added per TUV's request. Appendix 1 Product Descriptions were updated to reflect Agile for all SKUs. Formatting and editorial changes to align with FM-DVDP1509-01.105. Document revision number reassigned from 0xx to 1xx to align with DVSOP2005.	Thomas Saladin	28-OCT-2019