

	Declaration of Conformity	DoC-205 Revision Number: 105
	S1100: Respiratory Lung Expansion 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® EzPAP® airway therapy systems

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: 28 AUG 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.	23-0747	EZPAP W/ MOUTHPIECE NS	Smiths Medical ASD, Inc. 6250 Shier Rings Road, Dublin, OH, 43016, United States	57816	Ila	5
2.	23-0757	EZPAP W/ DISPOSABLE MANOMETER NS	Smiths Medical ASD, Inc. 6250 Shier Rings Road, Dublin, OH, 43016, United States	57816	Ila	5
3.	23-1747	EZPAP W/ PEDIATRIC MASK NS	Smiths Medical ASD, Inc. 6250 Shier Rings Road, Dublin, OH, 43016, United States	57814	Ila	2
4.	23-2747	EZPAP W/ MEDIUM MASK NS	Smiths Medical ASD, Inc. 6250 Shier Rings Road, Dublin, OH, 43016, United States	57814	Ila	2
5.	23-3747	EZPAP W/ LARGE MASK NS	Smiths Medical ASD, Inc. 6250 Shier Rings Road, Dublin, OH, 43016, United States	57814	Ila	2

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Appendix 2: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date (DD-MMM-YYYY Format)
004	Initial release. Separated the above SKU's from DoC-086 as their Legal Manufacturer is Keene and is covered under different certificate. Removed the SKU 23-6000 as it does not have the CE mark.	Manasa Boppana	13-OCT-2017
105	Updated template to latest revision (from 002 to 105). Changed the legal manufacturer from MKEE to MMSP as per FM-DVSOP8005-05. 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. Added "Portex® EzPAP® airway therapy systems" as Product Tradename to reflect the affected SKUs. 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 660824 to 669121 due to the Legal Manufacturer change. Changed the Dublin's Manufacturing Site address to match the address listed on CE Certificate 669121.	Thomas Saladin	26-AUG-2019