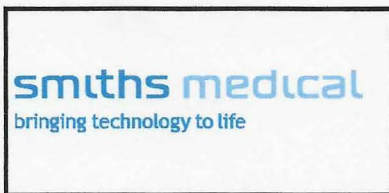


|                                                                                  |                                           |                                 |
|----------------------------------------------------------------------------------|-------------------------------------------|---------------------------------|
|  | <b>Declaration of Conformity</b>          | DoC-086<br>Revision number: 107 |
|                                                                                  | S1100: Respiratory Lung Expansion Devices |                                 |

**Legal Manufacturer:**

Smiths Medical ASD, Inc.  
 6000 Nathan Ln. N  
 Minneapolis, MN 55442 USA

**EU Representative:**

Smiths Medical Czech Republic a. s.  
 Olomoucká 306,  
 Hranice 1 - Město,  
 753 01 Hranice, Czech Republic

**Product Tradename(s):**

Portex® Coach 2® incentive spirometers, Coach 2 For Kids®  
 incentive spirometers, Portex® DHD CliniFLO® breathing exerciser

**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 097063 0012 Rev. 00

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:



Date:

29-MAR-2021

Name: Brian Schmidt

Title: Director, Regulatory Affairs

Location of Signatory: Minneapolis, MN, US

Controlled Copy – Verify Revision & Effective Date are current before use

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|  | <b>Declaration of Conformity</b>          | DoC-086<br>Revision number: 107 |
|                                                                                   | S1100: Respiratory Lung Expansion Devices |                                 |

## Appendix 1: Revision History

| Revision Number | Summary of Changes / Additions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Created / Revised by | Date        |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|-------------|
| 002             | Update notified body certificate information, update to latest DoC template revision                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Breanna Fautsch      | 02-NOV-16   |
| 003             | Change Legal Manufacturer from St. Paul to Minneapolis. Omitted SKUs under Keene Legal Manufacture which will transfer to DoC S1100-2.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Amanda Haider        | 03-MAY-2017 |
| 004             | 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 S1100 to DoC-086 and revision from 003 to 004 and added STED # to header for traceability to STED. Added columns (UMDNS, GIVD, and IVD Classification) as they are on the DoC Rev 002 template. Remove Legal Manufacturer column as it is not required nor is it on the DoC Rev 002 template. Removed "Incentive Spirometer" from the GMDN code as only the code is required.                                                                                                                                     | Stacy Novak          | 23JUN2017   |
| 005             | Changed the Authorized Signatory, Group on EC certificate. Edited the conformity assessment and removed the issued on date.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Manasa Boppana       | 10-OCT-2017 |
| 106             | 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. Updated to latest template revision (from 002 to 105). Revised Dublin manufacturing site address to match MDSAP ISO 13485:2016. Added "Portex® Coach 2® incentive spirometers, Coach 2 For Kids® incentive spirometers, Portex® DHD CliniFLO® breathing exerciser" to reflect the tradename of the affected SKUs. | Madi Johnson         | 28-OCT-2019 |

|                                                                                   |                                           |                                 |
|-----------------------------------------------------------------------------------|-------------------------------------------|---------------------------------|
|  | <b>Declaration of Conformity</b>          | DoC-086<br>Revision number: 107 |
|                                                                                   | S1100: Respiratory Lung Expansion Devices |                                 |

| Revision Number | Summary of Changes / Additions                                                                                                                                                                                                                                                                                                                                                        | Created / Revised by | Date        |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|-------------|
|                 | <p>Changed product descriptions to match the descriptions in Agile.</p> <p>Changed the STED Title from "Bronchial Hygiene and Lung Expansion" to "Respiratory Lung Expansion Devices" to match the description in Agile.</p> <p>Added TUV address to "Notified Body" field per TUV's request.</p> <p>Document revision number reassigned from 0xx to 1xx to align with DVSOP2005.</p> |                      |             |
| 107             | <p>Update to EC Certificate Number to align with new TUV certificate received.</p> <p>Formatting and editorial changes per FM-DVDP1509-01.107, which includes transferring the SKUs from Appendix 1 to Attachment 1.</p>                                                                                                                                                              | Ashley Levang        | 25-MAR-2021 |