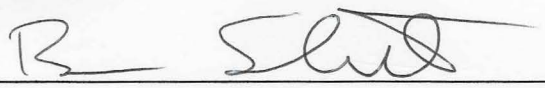
smiths medical bringing technology to life	**Declaration of Conformity** S1100: Respiratory Lung Expansion Devices	DoC-086 Revision number: 107

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

[logo:] Smiths medical bringing technology to life [zmieniamy technologię w życie]	**Deklaracja zgodności**	DoC-086 Wydanie numer: 107
	S1100: Urządzenia do rozprężania płuc	

Producent	Smiths Medical ASD, Inc., 6000 Nathan Lane North Minneapolis, Minnesota 55442, USA
Przedstawiciel w UE (jeśli dotyczy)	**Smiths Medical Czech Republic a. s.** **Olomoucká 306,** **Hranice 1 – Mesto,** **753 01 Hranice, Czech Republic**
Nazwa handlowa Produktu	Spirometr objętościowy Portex® Coach2®, Spirometr objętościowy Portex® Coach2® dla dzieci, Urządzenie do ćwiczeń oddechowych Portex® DHD CliniFlo®
Metoda Oceny Zgodności	Załącznik II (z wyłączeniem sekcji4)
Jednostka Notyfikowana	TUV SUD Product Service GmbH Zertifizierenstellen Riedlerstraβe 65 80339 Munchen Niemcy Jednostka Notyfikowana #0123
Numer certyfikatu CE	G1 097063 012 Rev.00

Smiths Medical ASD, Inc. niniejszym oświadcza, że te produkty są zgodne z odpowiednimi przepisami dyrektywy Parlamentu Europejskiego i Rady 93/42/EWG dotyczącej Wyrobów Medycznych (MDD) oraz ze zmianami wprowadzonymi przez dyrektywę 2007/47/WE.

Załącznik 1 dla listy objętych numerów

Autoryzowany Sygnatariusz:

Podpis: /-/ Imię i nazwisko: Brian Schmidt Tytuł: Dyrektor ds. Regulacyjnych Miejsce podpisania dokumentu: Minneapolis, MN, USA	Data: 29 marca 2021r.

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

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

DoC-086 SKU List

Revision Number: 107

Catalog Number	Product Description	GMDN Code	EU Risk Class	EU Rule
22-2000	Coach 2 for Kids NS	31266	IIa	5
22-2500	Coach 2 2500ml NS	31266	IIa	5
22-2501	Coach 2 2500ml W/O Valve NS	31266	IIa	5
22-4000	Coach 2 4000ml NS	31266	IIa	5
22-4001	Coach 2 4000ml W/O Valve NS	31266	IIa	5
22-1200	Cliniflo Lung Exerciser, Low Flow NS	31266	IIa	5