smiths medical bringing technology to life	**Declaration of Conformity** S1289: acapella Choice Blue Vibratory PEP Device	DoC-324 Revision Number: 101

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):	acapella Choice Blue Vibratory PEP Device
Product Scope:	Vibratory Positive Expiratory Devices
Conformity Assessment Route:	Annex II (excluding Section 4)
Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65, 80339 München, Germany Notified Body #0123
EC Certificate Number:	G1 097063 0012 Rev. 00
Start of CE-Marking:	15-NOV-2019

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: B Schmidt Date: 24-MAR-2021

Name: Brian Schmidt

Title: Director, Regulatory Affairs

Location of Signatory: Minneapolis, Minnesota, USA

FM-DVDP1509-01 Rev. 107 Eff. Date: 19-MAR-2020 CO No.: CO-10095397

27-8000	acapella Choice Blue Vibratory PEP Device	43947	IIa	5
27-8001	acapella Choice Blue Vibratory PEP Device	43947	IIa	5
27-8050	Mouthpiece acapella Choice Blue	43947	IIa	5