

	Declaration of Conformity	DoC-324
	S1289: acapella Choice Blue Vibratory PEP Device	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

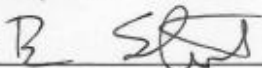
EC Certificate Number: G1 097063 0012 Rev. 00

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:  Date: 24-MAR-2021

Name: Brian Schmidt

Title: Director, Regulatory Affairs

Location of Signatory: Minneapolis, Minnesota, USA

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