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Declaration of Conformity


Manufacturer: DeVilbiss Healthcare LLC
Address: 100 DeVilbiss Drive, Somerset, PA 15501
Product Designation: CPAP UMDNS 11-001
Type, Model: DeVilbiss BLUE Standard Plus
DV63E-AU
DV63E-DEN
DV63E-G
DV63E-NE
DV63E-NOR
DV63E-SE
DV63E-UK

We herewith declare that the above mentioned product complies with the requirements of EC Directive 93/42/EEC + A2007 Annex II, Radio Equipment Directive 2014/53/EU and RoHS Directive 2011/65/EC & REACH Regulation (EC) No 1907/2006.

Class: IIa, Rule 2
Quality System Standards applied: EN ISO 13485:2012 + AC:2012
Notified Body: TUV NORD CERT GmbH
Langemarkstrasse 20
45141 Essen
Germany

European Representative:  0044
DeVilbiss Healthcare GmbH
Kamenzerstraße 3
68309 Mannheim
Germany
Phone: +49 (0) 621-178-98-0

EC Certificate: 44 232 117803
EC Certificate Expiration Date: 6 August 2019

Place: Somerset, PA
Signature: 
Name: Dourene A. Gobbel
Title: Quality Manager
Date: 15 May 2017