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Declaration of Conformity

Manufacturer:

DeVilbiss Healthcare

Address:

100 DeVilbiss Drive, Somerset, PA 15501

Product Designation:

Oxygen Delivery Units Accessories

UMDNS 18-076

Type, Model:

iFill Oxygen Cylinders w/integrated PulseDose Regulator:

PD1000A-I-ML6, PD1000A-I-C, PD1000A-I-D, PD1000A-I-E

iFill Oxygen Cylinders w/ continuous Flow Regulator:

535i-ML6-CF, 535i-C-CF, 535i-D-CF, 535i-E-CF

EX3000D-653 M6 Cylinder Carrying Case EX3000D-654 ML6 Cylinder Carrying Case EX3000D-651 C Cylinder Carrying Case EX3000D-652 D Cylinder Carrying Case

CT001 E Cylinder Cart

PD1000A-627 Cylinder Nipple Dust Cap

We herewith declare that the above mentioned product complies with the requirements of EC Directive 93/42/EEC + A2007 Annex II 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

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45141 Essen Germany

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EC Certificate:

44 232 117803

EC Certificate Expiration Date:

6 August 2019

Place:

Somerset, PA

Signature:

Dourene A. Gobbel

Name: Title:

Quality Manager

Date:

22 July 2016

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