EC Declaration of Conformity

Manufacturer: *DeVilbiss Healthcare LLC*
100 DeVilbiss Drive
Somerset, PA 15501, USA

EC Authorized Representative: *DeVilbiss Healthcare GmbH*
Kamenzerstraße 3, 68309
Mannheim, Germany

1. ***Oxygen Delivery Units, controlled*** (UMDNS ***18-076***):
Catalogue nos.: *535I*
PD1000I, PD1000G

Classification (MDD Annex IX): *IIa (Rule 11)*
Conformity Assessment Procedure: *MDD 93/42/EEC, Annex II excluding Section 4*

2. Accessories:
Product Description (Catalogue no.):

ML6 Cylinder w/CF Regulator, Europe	*535I-ML6-CF*
C Cylinder w/CF Regulator, Europe	*535I-C-CF*
D Cylinder w/CF Regulator, Europe	*535I-D-CF*
E Cylinder w/CF Regulator, Europe	*535I-E-CF*
Cabinet Air Filter, 6 pk.	*535D-605*
Bag, C Cylinder	*EX3000D-651*
Bag, D Cylinder	*EX3000D-652*
Bag, M-6 Mini Cylinder	*EX3000D-653*
Bag, ML6 Cylinder	*EX3000D-654*
Cylinder Nipple Dust Cap, 5 pk.	*PD1000A-627*
Covers, Top & Bottom replacement	*PD1000A-601*
Gauge Kit	*PD1000A-620*
Gauge Kit	*PD1000G-620*
Seal, Regulator, 10 pk.	*PD1000G-618*
PD1000A w/C Cylinder, Europe	*PD1000A-I-C*
PD1000A w/D Cylinder, Europe	*PD1000A-I-D*
PD1000A w/E Cylinder, Europe	*PD1000A-I-E*

Applied standards: All applicable harmonized standards as adopted under the EC Directive 93/42/EEC and published in the Official Journal of the European Communities. *(See attached listing)*

This Declaration of Conformity is based on the EC Directive 93/42/EEC, Annex II.3 and supported by the TÜV NORD CERT GmbH (0044) certificate, with reference to articles 1 and 3 of the directive 93/42/EEC.

Notified Body: *TÜV NORD CERT GmbH*
Langemarckstrasse 20, 45141 Essen, Germany

Identification No.: *0044*
EC Certificate No.: *44 232 117803*
Start of EC Marking: *2002-06-19*

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We, DeVilbiss Healthcare LLC., hereby declare under our sole responsibility that the above-mentioned products comply with the essential requirements and provisions of Council Directive 93/42/EEC.

Validity of this Declaration: *2019-08-07 – 2024-05-26*

Somerset, PA, June 3, 2022

Place, Date

Roberto Munoz Director, Regulatory Affairs and Audit

Name and Position

Applied Standards:

535 series
IEC 60601-1:2005+A1:2012 Medial electrical equipment — Part 1 General requirements for basic safety
IEC 60601-1-2:2014, Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic compatibility – Requirements and tests (FDA Recognition Number 19-8)
IEC 60601-1-6:2010 + AMD 1:2013 Ed. 3.1 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (associated with IEC 60601-1 Ed. 3.0) (FDA Recognition Number 5-89)
IEC 60601-1-9:2007 + A1:2013 Ed. 1.1 Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral standard: Requirements for environmentally conscious design (associated with IEC 60601-1 Ed. 3.0)
IEC 60601-1-11:2015 (Ed 2.0), Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment (FDA Recognition Number19-14)
IEC 62366:2007 Ed. 1.0 + AMD 1:2014 – Medical devices - Application of usability engineering to medical devices (FDA Recognition number 5-87)
IEC 62304:2006 + AMD1:2015: Ed. 1.1 - Medical device software - Software life cycle processes (FDA Recognition number 13-79)
BS EN ISO 14971:2012 Medical devices - Application of risk management to medical devices (FDA Recognition number 5-40 is to ISO 14971:2007
ISTA Procedure 3A: Packaged-Products for Parcel Delivery System Shipments 70kg (150 lb) or less (standard).
ASTM G63-15 Standard Guide for Evaluating Nonmetallic Materials for Oxygen Service
ASTM G94-05 Standard Guide for Evaluating Metals for Oxygen Service
BS EN ISO 15001:2011 Anaesthetic and respiratory equipment. Compatibility with oxygen

PD1000 series
Compressed Gas Association: CGA G 4-1 Section 8.2; CGA G 4-1 Section 11.2.2
AIR PRODUCTS Oxygen Clean (Class AA) requirements; 4WPI-SW70003
EN 738-1; Pressure Regulators for use with medical gases. Part 1: Pressure regulators and pressure regulators with flow metering devices for medical gas systems
ISO 407; Small medical gas cylinders – Pin -index yoke-type valve connections
BS341; Transportable gas container valves
EMC; IEC 801-2, 801-3 & CISPR 11
IEC 601-1: 1988, IEC 601-1: 1988 Amendment 1 & 2, IEC 601-1-2: 1993-04
IEC 68-2; Shock & Vibration Requirements
IEC 529 2ND Characteristic numeral 1; Protection against Vertical dripping water
ISTA (International Safe Transit Association) Shipping Test (Refer to Section 10.2)
ASTM PS127-00, Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators Used for Medical and Emergency Applications
CGA C-7 precautionary labeling and marking of compressed gas containers
CGA C-9 standard color marking of compressed gas containers intended for medical use
ISO 18779:2005(E) Medical devices for conserving oxygen mixtures—Particular Requirements