

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

**2. Accessories:**

Product Description (Catalogue no.):

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

**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

# EC Declaration of Conformity

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.

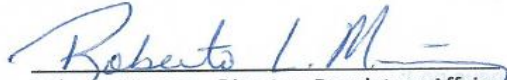
**Validity of this Declaration:**

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:**

<b>535 series</b>
IEC 60601-1:2005+A1:2012 Medical 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 Number 19-14)
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
<b>PD1000 series</b>
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