

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 Concentrators (UMDNS 12-873)

Catalogue nos.: *1025KS, 1025UK*
Description: *Drive DeVilbiss® 10-Liter Oxygen Concentrator*
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>Caster, 4 pkg.-DFT</i>	<i>501DZ-603</i>
<i>Flow Meter Pkg., Low Output</i>	<i>515LF-607</i>
<i>Caster, Locking, 2 pk.</i>	<i>525DS-603</i>
<i>Cabinet Air Filter</i>	<i>303DZ-605</i>
<i>Intake Bacteria Filter</i>	<i>1025D-605</i>
<i>Compressor Filter</i>	<i>1025D-682</i>
<i>Sieve Bed, 2 pk.</i>	<i>1025D-619</i>
<i>230V Compressor SSP</i>	<i>1025K-625</i>
<i>Final Bacteria Filter</i>	<i>PV5LD-651</i>
<i>Transfill Hose</i>	<i>PF1100TUB</i>
<i>Oxygen outlet connector (plastic, 1/pack)</i>	<i>CN100</i>
<i>Transfill Caddy</i>	<i>525DD-650</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
0044*
Identification No.: *44 232 117803*
EC Certificate No.: *2017-11-15*
Start of EC Marking:

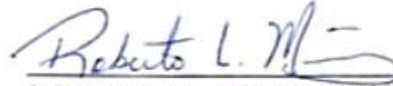
We, DeVilbiss Healthcare LLC., hereby declare under our sole responsibility that the above-mentioned products comply with the essential requirements and provisions of Council Directive 93/42/EEC.

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Validity of this Declaration:

2019-08-07 – 2024-05-26

Somerset, PA, 26-Oct-2022



Place Date

Roberto Munoz Director, Regulatory Affairs & Audits
Name and Position

Applied standards:

1025KS / 1025UK

AAMI / ANSI ES60601-1:2005/(R) 2012 Ed 3.1 and A1:2012, C1:2009/(R) 2012 and A2:2010/(R) 2012 (Consolidated Text) Medical Electrical Equipment—Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005, Mod). (General I (QS/RM))

AAMI / ANSI / IEC 60601-1-2:2014, Ed. 4.0, Medical Electrical Equipment—Part 1-2: General Requirements for Basic Safety And Essential Performance – Collateral Standard; Electromagnetic Disturbances - Requirements and Tests (associated with IEC 60601-1 Ed. 3.0)

IEC 60601-1-8 Ed. 2.1 b.2012 Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (associated with IEC 60601-1 3rd Edition)

IEC 60601-1-11:2010 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 (associated with IEC 60601-1 3rd Edition, referenced by ISO 80601-2-69:2014)

AAMI / ANSI / IEC 62304:2006, Medical Device Software – Software Life Cycle Process (Software/Informatics)

ISO 80601-2-69:2014 Medical electrical equipment – Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment

ISTA Procedure 6A FedEx Packaged-Products for Parcel Delivery System Shipments 70kg (150 lb) or Less (standard)

AMMI / ANSI / ISO 10993-1:2009, Biological Evaluation Of Medical Devices – Part 1: Evaluation And Testing Within A Risk Management Process (Biocompatibility)