EC Declaration of Conformity

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

EC Authorized Representative:
Drive Medical GmbH & Co. KG
Leutkircher Str. 44
DE-88316 Isny im Allgau

1. Oxygen Concentrators (UMDNS 12-873)

Catalogue nos.:	*1025KS, 1025UK*
Description:	*Drive DeVilbiss® 10-Liter Oxygen Concentrator*
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.):

Caster, 4 pkg.-DFT	*501DZ-603*
Flow Meter Pkg., Low Output	*515LF-607*
Caster, Locking, 2 pk.	*525DS-603*
Cabinet Air Filter	*303DZ-605*
Intake Bacteria Filter	*1025D-605*
Compressor Filter	*1025D-682*
Sieve Bed, 2 pk.	*1025D-619*
230V Compressor SSP	*1025K-625*
Final Bacteria Filter	*PV5LD-651*
Transfill Hose	*PF1100TUB*
Oxygen outlet connector (plastic, 1/pack)	*CN100*
Transfill Caddy	*525DD-650*

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: *2017-11-15*

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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Somerset, PA, 02 September 2024
Place Date

Zita A. Yurko, RAC
Sr. Director Regulatory Affairs
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 Medial 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)