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.:	*125K, 125K-XB*
Description:	*Drive DeVilbiss iGo®2 Portable 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.):

Spare Battery	*125D-613*
Power Supply 120 Watt (AC/DC Adapter)	*DV68-620*
Carry Case	*125D-670*
AC Power Cord, USA	*DV51D-606*
AC Power Cord, EU	*DV51D-607*
AC Power Cord, UK	*DV51D-608*
AC Power Cord, AU	*DV51D-609*
AC Power Cord, CN	*DV51D-614*
DC Power Cord (Auto Adapter)	*DV6X-619*
External Battery Charger, USA	*125CH-613*
External Battery Charger, Continental Europe	*125CH-614*
External Battery Charger, UK	*125CH-615*
Sieve Bed Package	*125D-619*
Cabinet Screws, 6 pk.	*125D-621*
O2 Port & Bacteria Filter	*125D-610*

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: *2019-08-07*

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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, 14-Feb-2022

Place Date

Roberto L. M

Roberto Munoz Director, Regulatory Affairs and Audits

Name and Position

Applied Standards:

125K
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).
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 60601-1-6:2010 + 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)
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)
AAMI / ANSI / IEC 62304:2006 + AMD 1:2015, Medical Device Software – Software Life Cycle Process (Software/Informatics)
IEC 62366:2007 Ed. 1.0 + AMD 1:2014 – Medical devices - Application of usability engineering to medical devices
ISO 80601-2-69:2014 Medial electrical equipment – Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment
ISO 80601-2-67:2014 Medical electrical equipment – Part2-67: Particular requirements for basic safety and essential performance of oxygen conserving equipment
ISTA Procedure 3A: Packaged-Products for Parcel Delivery System Shipments 70 kg (150 lb) or Less (standard)
RTCA/DO-160G section 21, category M - Environmental Conditions and Test Procedures for Airborne Equipment
RTCA/DO-160G section 20, Radio Frequency Susceptibility – Radiated only 100 MHz up to 18 GHZ