

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
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, Australia	DV51D-609
AC Power Cord, China	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

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,

Dec. 21, 2020

Place

Date



Tejash Naik Senior Director, Regulatory Affairs and Quality Assurance
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 Medical 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 – Part 2-67: 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