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.:	*125A, 125K, 125K-XB*
Description:	*125A-BT, 125K-BT, 125K-BT-XB*
	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, US	*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.

Somerset, PA, 02 September 2024
Place Date

Zita A. Yurko, RAC
Sr. Director Regulatory Affairs
Name and Position

Applied Standards:

125A, 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
Device Air Purity testing per ISO 18562:2017 (Parts 1 through 3) Biocompatibility evaluation of breathing gas pathways in healthcare applications *(FDA Recognition Number 1-134)*
AMMI / ANSI / ISO 10993-1:2009, Biological Evaluation Of Medical Devices – Part 1: Evaluation And Testing Within A Risk Management Process (Biocompatibility) (FDA Recognition Number 2- 156)
ISO 14971:2019, Medical devices - Application of risk management to medical devices [FDA Recognized Consensus Standard]
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

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125A-BT, 125K-BT
ISO 80601-2-67:2014, Medical Electrical Equipment - Part 2-67: Particular requirements for basic safety and essential performance of oxygen conserving equipment (FDA Recognition Number 1-102)
ISO 80601-2-69:2014, Medical electrical equipment - Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment
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 (FDA Recognition Number 19-4)
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 (FDA Recognition Number 19-8)
IEC 60601-1-6:2010 +A1:2013 Ed. 3.1 – Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability (FDA Recognition Number 5-89) This version cited by the ISO particular standards -67 & -69.
IEC 60601-1-8:2006 +A1:2012 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 (FDA Recognition Number 5-76)
IEC 60601-1-11:2010 + Corr 1:2011 - 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 (FDA Recognition Number 19-14 for IEC Ed 2.0 version)
IEC 60068-2-2: 2007, Environmental testing – Part 2-2: Tests – Test B: Dry heat
IEC 60529:1989 +A1:199, Classification of Degrees of Protection Provided by Enclosures
AAMI / ANSI / IEC 62304:2006 + AMD1:2015: Ed. 1.1 - Medical device software - Software life cycle processes (FDA Recognition number 13-79)
IEC 62366:2007 +A1:2014 – Application to usability engineering to medical devices (FDA Recognition number 5-87)
ISO 14971:2019, Medical devices - Application of risk management to medical devices [FDA Recognized Consensus Standard]
ISTA Procedure 3A: Packaged-Products for Parcel Delivery System Shipments 70kg (150 lb) or less
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.
AAMI TIR 69 Risk management of radio-frequency wireless coexistence for medical devices and systems
ANSI C63.27 American National Standard for Evaluation of Wireless Coexistence
Device Air Purity testing per ISO 18562:2017 (Parts 1 through 3) Biocompatibility evaluation of breathing gas pathways in healthcare applications (FDA Recognition Number 1-134)
AMMI / ANSI / ISO 10993-1:2009, Biological Evaluation Of Medical Devices – Part 1: Evaluation And Testing Within A Risk Management Process (FDA Recognition Number 2-156)
14-1 10/2018 MDS-Hi – Determining the operating volume for oxygen concentrators/filling stations
European Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE)
General Data Protection Regulation (GDPR) 2016/679
European Radio Equipment Directive 2014/53/EU