

# 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. CPAP Units (UMDNS 11-001):**  
 Catalogue nos.: DV64E-DEN, DV64E-DEN-HH, DV64E-DEN-HHPD,  
 DV64E-G, DV64E-G-HH, DV64E-G-HHPD,  
 DV64E-NE, DV64E-NE-HH, DV64E-NE-HHPD,  
 DV64E-NOR, DV64E-NOR-HH, DV64E-NOR-HHPD,  
 DV64E-SE, DV64E-SE-HH, DV64E-SE-HHPD,  
 DV64E-UK, DV64E-UK-HH, DV64E-UK-HHPD

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.):

Heated Humidifier w/ Standard Humidification	DV6HH
Heated Humidifier w/ PulseDose Humidification upgrade	DV6HHPD
Humidifier Water Chamber	DV6C
Power Cord, Europe	DV51D-607
Power Cord, UK	DV51D-608
Power Cord, Australia	DV51D-609
Power Cord, USA	DV51D-606
Carry Case	DV63D-610
Air Inlet Filter Pkg., 4 pk., Gray	DV51D-602
Fine Particle Air Filter Pkg., 4 pk., White	DV51D-603
Power Supply	DV63D-613
Air Supply Port Cover	DV61D-604
Filter Cover	DV63D-631
12V Adapter w/ Clips	DV51D-696
DC Power Cord (Cigarette Lighter Adapter)	DV6X-619
Air Supply Tubing, 6" 22 mm	DV51D-629
Air Supply Tubing, 6" 15 mm	DV61D-629
Oxygen Adapter	7353D-601
CPAP Tubing, 8' (2.4m), 22mm (SB)	7353D-603
Inline Bacteria Filter, Elbow, Tubing Kit	DV51D-631
Clinical Module Assy.	DV6CM
Wireless Modem	DV6WM-EU
Wireless Modem	DV6WM-UK
Wall Charger Micro USB w/ Europe Plug	DV6WM-410-EU
Wall Charger Micro USB w/ UK Plug	DV6WM-410-UK

**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)

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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:** 2015-09-18

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, Jan 14, 2022  
Place, Date

Roberto L. Munoz  
Roberto Munoz Director, Regulatory Affairs and Audits  
Name and Position

**Applied Standards:**

<b>DV64 series</b>
ISO 80601-2-70:2015 Medical electrical equipment — Part 2-70 Particular requirement for basic safety and essential performance of sleep apnea breathing therapy equipment (FDA Recognition Number 1-115)
ISO 8185:2007 - Third Edition 2007-07-01 Respiratory tract humidifiers for medical use — Particular requirements for respiratory humidification systems
IEC 60601-1:2005 Ed. 3.0 + A1:2012 - Medical Electrical Equipment—Part 1: General Requirements for Safety; Safety Requirements for Medical Electrical Systems
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 Compatibility – Requirements and Tests (Edition 3)
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) (FDA Recognition Number 5-89)
IEC 60601-1-9:2007 + A1:2013 Ed. 1.1 Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral standard: Requirements for environmentally conscious design (associated with IEC 60601-1 Ed. 3.0)
IEC 60601-1-11:2015 (Ed 2.0), 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 (FDA Recognition Number 19-14)
IEC 62366:2007 Ed. 1.0 + AMD 1:2014 – Medical devices - Application of usability engineering to medical devices (FDA Recognition number 5-87)
IEC 62304:2006 + AMD1:2015: Ed. 1.1 - Medical device software - Software life cycle processes (FDA Recognition number 13-79)
ISO 14971:2019 (Third Ed), Medical devices - Application of risk management to medical devices [FDA Recognized Consensus Standard Number 5-125]
ISTA Procedure 3A: Packaged-Products for Parcel Delivery System Shipments 70kg (150 lb) or less (standard).