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.: *DV57NE, DV57SE, DV57SE-HH, DV57UK, DV57UK-HH*

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.):

Humidifier Chamber	*DV5C*
Chamber Sealing Gasket	*DV5C-614*
Heated Humidifier Kit assembly, w/Chamber	*DV5HH*
Smart Link Module	*DV5M*
Smart Link w/Data Card	*DV5M-FC-1*
Power Cord, Europe	*DV51D-607*
Power Cord, UK	*DV51D-608*
Power Cord, Australia	*DV51D-609*
Power Cord, USA	*DV51D-606*
Air Inlet Filter Pkg., 4 pk., Gray	*DV51D-602*
Fine Particle Air Filter Pkg., 4 pk., White	*DV51D-603*
Carry Case, DV5x series CPAP	*DV51D-610*
DC Power Cord	*DV51D-619*
12V Adapter w/ Clips	*DV51D-696*
Air Supply Port Plug	*DV51D-604*
Heater Connector Cover	*DV51D-605*
Air Supply Tubing, 6" 22 mm	*DV51D-629*
Serial Cable, for direct connect	*DV51D-615*
ISB to Serial Adapter Cable, for direct connect	*DV51D-691*
ABOB Interface Cable	*DV51D-690*
Smart Link USB Extension Cable	*DV51D-694*
Oxygen Adapter	*7353D-601*
CPAP Tubing, 8' (2.4m), 22mm (SB)	*7353D-603*
Bacteria Filter, Elbow, Tubing Kit	*DV51D-631*
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:	*2011-11-22*

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 Munoz Director, Regulatory Affairs and Audits
Name and Position

Applied Standards:

DV57 series
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 Number19-14)
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).