

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.: *DV53NE, DV53SE, DV53SE-HH, DV53UK*

 Classification (MDD Annex IX): *Ila (Rule 11)*
 Conformity Assessment Procedure: *MDD 93/42/EEC, Annex II excluding Section 4*

2. Accessories:
 Product Description (Catalogue no.):

<i>Humidifier Chamber</i>	<i>DV5C</i>
<i>Chamber Sealing Gasket</i>	<i>DV5C-614</i>
<i>Heated Humidifier Kit assembly, w/Chamber</i>	<i>DV5HH</i>
<i>Smart Link Module</i>	<i>DV5M</i>
<i>Smart Link w/Data Card</i>	<i>DV5M-FC-1</i>
<i>Power Cord, Europe</i>	<i>DV51D-607</i>
<i>Power Cord, UK</i>	<i>DV51D-608</i>
<i>Power Cord, Australia</i>	<i>DV51D-609</i>
<i>Power Cord, USA</i>	<i>DV51D-606</i>
<i>Air Inlet Filter Pkg., 4 pk., Gray</i>	<i>DV51D-602</i>
<i>Fine Particle Air Filter Pkg., 4 pk., White</i>	<i>DV51D-603</i>
<i>Carry Case, DV5x series CPAP</i>	<i>DV51D-610</i>
<i>DC Power Cord</i>	<i>DV51D-619</i>
<i>12V Adapter w/ Clips</i>	<i>DV51D-696</i>
<i>Air Supply Port Plug</i>	<i>DV51D-604</i>
<i>Heater Connector Cover</i>	<i>DV51D-605</i>
<i>Air Supply Tubing, 6" 22 mm</i>	<i>DV51D-629</i>
<i>Serial Cable, for direct connect</i>	<i>DV51D-615</i>
<i>USB to Serial Adapter Cable, for direct connect</i>	<i>DV51D-691</i>
<i>ABOB Interface Cable</i>	<i>DV51D-690</i>
<i>Smart Link USB Extension Cable</i>	<i>DV51D-694</i>
<i>Oxygen Adapter</i>	<i>7353D-601</i>
<i>CPAP Tubing, 8' (2.4m), 22mm (SB)</i>	<i>7353D-603</i>
<i>Bacteria Filter, Elbow, Tubing Kit</i>	<i>DV51D-631</i>
<i>Wireless Modem</i>	<i>DV6WM-EU</i>
<i>Wireless Modem</i>	<i>DV6WM-UK</i>
<i>Wall Charger Micro USB w/ Europe Plug</i>	<i>DV6WM-410-EU</i>
<i>Wall Charger Micro USB w/ UK Plug</i>	<i>DV6WM-410-UK</i>

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: 2010-03-24

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 18, 2022
Place, Date

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

Applied Standards:

DV53 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 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).