

# 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. Suction Units (UMDNS 13-846):**  
Catalogue nos.: *7310PR-D, 7310PR-I, 7310PR-S, 7310PD-S, 7310PD-PS*

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>6' Patient Tubing</i>	<i>6305D-611</i>
<i>300 cc Single Use Canister, 10 pk.</i>	<i>7310D-630</i>
<i>300 cc Single Use Canister, single pk.</i>	<i>7310D-631</i>
<i>Battery, replacement, 1 ea.</i>	<i>7310P-601</i>
<i>Battery Door</i>	<i>7310P-602</i>
<i>Carry Case w/Shoulder Strap</i>	<i>7310P-606</i>
<i>725 ml Reusable Container Kit (Jar, Lid/Elbow assembly, Filter)</i>	<i>7310P-603</i>
<i>External Bacteria Filter (non-sterile), 12 pk. (for reusable container use)</i>	<i>7305D-608</i>
<i>AC to DC adapter/charger</i>	<i>7314P-613</i>
<i>DC Power Cord, 1 each</i>	<i>7304D-619</i>
<i>Power Cord, USA</i>	<i>DV51D-606</i>
<i>Power Cord, Continental 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, Brazil</i>	<i>DV51D-612</i>
<i>Power Cord, Japan</i>	<i>DV51D-613</i>
<i>Power Cord, China</i>	<i>DV51D-614</i>
<i>Power Cord, Argentina</i>	<i>180-0006-011</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)*

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:** *01-09-2008*

# EC Declaration of Conformity

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, June 3, 2022  
*Place, Date*

  
 Roberto Munoz Director, Regulatory Affairs and Audit  
*Name and Position*

**Applied Standards:**

<b>7310 series</b>
EN ISO 10079-1:2015/Amd. 1:2018+A1:2012 Ed.3 Medical Suction Equipment-Part 1:Electrically Powered Suction Equipment
IEC 60601-1:2005+A1:2012 Medical electrical equipment — Part 1 General requirements for basic safety (FDA Recognition Number 1-115)
IEC 60601-1-2:2014, Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic compatibility – Requirements and tests (FDA Recognition Number 19-8)
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 60601-1-11:2015 (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 60068-2-6 Issued:2007/12/01 Ed:7.0 Environmental Testing-Part 2-6:Tests-Test Fc: Vibration (sinusoidal)
IEC 60068-2-27 Issued 2008/02/01 Ed:4.0 Environmental Testing-Part 2-27: Tests-Test Ea and guidance: Shock
IEC 60068-2-34 Issued 1973/01/01 Ed.1 Basic Environmental Testing Procedures Part 2: Tests Test Fd: Random Vibration Wide Band-General Requirements
IEC 62133-1:2017, Ed. 1.0 – Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications – Part 1: Nickel systems
IEC 62366:2007 Ed. 1.0 + AMD 1:2014 – Medical devices - Application of usability engineering to medical devices (FDA Recognition number 5-87)
BS EN ISO 14971:2012 Medical devices - Application of risk management to medical devices (FDA Recognition number 5-40 is to ISO 14971:2007)
IEC 60529 Issued 2001/02/01 Ed:2.1, Classification of Degrees of Protection Provided by Enclosures
ISTA 3A Packaged Product Testing: Dynamic Vibration, Drop Testing, Thermal Testing