# 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.: *7305D-D, 7305D-D-EXF, 7305D-G, 7305D-I, 7305D-LA, 7305P-D, 7305P-D-EXF, 7305P-F, 7305P-G, 7305P-I, 7305P-LA, 7305P-T, 7305P-U*

   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.):

| | |
|---|---|
| *6' Patient Tubing* | *6305D-611* |
| *Collection Container Kit (internal filter cartridge, splash guard, 800 ml container, 4 ⅜" and 6" tubing package)* | *7305D-633* |
| *800 ml Disposable Container w/ internal filter cartridge, splash guard, 4 ⅜" tubing, 48 each* | *7305D-632* |
| *Filter Cartridge, 12 pk. (for disposable container use)* | *7305D-635* |
| *Collection Container Kit (1200 ml reusable container, external bacteria filter, elbow, 4 ⅜" tubing)* | *7314D-603* |
| *1200 ml Reusable Container (external bacteria filter, elbow, 4 ⅜" tubing) 6 pk.* | *7314D-604* |
| *External Bacteria Filter (non-sterile), 12 pk. (for reusable container use)* | *7305D-608* |
| *Carry Case* | *7305D-606* |
| *AC to DC adapter/charger* | *7314P-613* |
| *DC Power Cord, 1 each* | *7304D-619* |
| *Power Cord, USA* | *DV51D-606* |
| *Power Cord, Continental Europe* | *DV51D-607* |
| *Power Cord, UK* | *DV51D-608* |
| *Power Cord, Australia* | *DV51D-609* |
| *Power Cord, Brazil* | *DV51D-612* |
| *Power Cord, Japan* | *DV51D-613* |
| *Power Cord, China* | *DV51D-614* |
| *Power Cord, Argentina* | *180-0006-011* |

   Classification (MDD Annex IX): *IIa (Rule 2)*
   Conformity Assessment Procedure: *MDD 93/42/EEC, Annex II excluding Section 4*

**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)*

# EC Declaration of Conformity

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*<br>*Langemarckstrasse 20, 45141 Essen, Germany* |
| **Identification No.:** | *0044* |
| **EC Certificate No.:** | *44 232 117803* |
| **Start of EC Marking:** | *25-09-1998* |

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,** August 9, 2019
*Place, Date*

Sandy Figueroa, Manager, Regulatory Affairs
*Name and Position*

**Applied Standards:**

| **7305 series** |
|---|
| EN ISO 10079-1:2015 Ed.3 Medical Suction Equipment-Part 1:Electrically Powered Suction Equipment |
| IEC 60601-1:2005+A1:2012 Medial electrical equipment — Part 1 General requirements for basic safety (FDA Recognition Number1-115) |
| 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 Number19-14) |
| IEC 60601-1-12:2014 Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment |
| 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 |
| 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 |
| ISTA 3A Packaged Product Testing: Dynamic Vibration, Drop Testing, Thermal Testing |