

EC Declaration of Conformity

Manufacturer: *DeVilbiss Healthcare LLC
100 DeVilbiss Drive
Somerset, PA 15501, USA*

EC Authorized Representative: *Drive Medical GmbH & Co. KG
Leutkircher Str. 44
DE-88316 Isny im Allgau*

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): *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>Collection Container Kit (internal filter cartridge, splash guard, 800 ml container, 4 3/8" and 6" tubing package)</i>	<i>7305D-633</i>
<i>800 ml Disposable Container w/ internal filter cartridge, splash guard, 4 3/8" tubing, 48 each</i>	<i>7305D-632</i>
<i>Filter Cartridge assy, 1 pk. (for 800ML disposable container use)</i>	<i>7305D-634</i>
<i>Filter Cartridge, 12 pk. (for 800ML disposable container use)</i>	<i>7305D-635</i>
<i>Collection Container Kit (1200 ml reusable container, external bacteria filter, elbow, 4 3/8" tubing)</i>	<i>7314D-603</i>
<i>1200 ml Reusable Container (external bacteria filter, elbow, 4 3/8" tubing) 6 pk.</i>	<i>7314D-604</i>
<i>External Bacteria Filter (non-sterile), 12 pk. (for reusable container use)</i>	<i>7305D-608</i>
<i>Carry Case</i>	<i>7305D-606</i>
<i>Battery, replacement assy</i>	<i>7305P-614</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.

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Notified Body: TÜV NORD CERT GmbH
 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.



Somerset, PA, 02 September
2024
 Place Date

 Zita A. Yurko, RAC
 Sr. Director 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 Medical 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