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.: *7314D-AP, 7314D-D, 7314D-D-EXF, 7314D-LA, 7314D-NE, 7314D-U, 7314P-AP, 7314P-D, 7314P-D-EXF, 7314P-LA, 7314P-NE, 7314P-NE-R, 7314P-U, 7314P-UR*

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 assy, 1 pk. (for 800 ml disposable container use)	*7305D-634*
Filter Cartridge, 12 pk. (for 800 ml 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*
Battery, w/ 2 pcs. 7314 Foam, replacement assy.	*7314P-614*
Carry Case	*7314D-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*

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:	*15-08-2012*

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:

7314 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 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