

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.:

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-U,
7314P-UR

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.):

6' Patient Tubing	6305D-611
Collection Container Kit (internal filter cartridge, splash guard, 800 ml container, 4 3/8" and 6" tubing package)	7305D-633
800 ml Disposable Container w/ internal filter cartridge, splash guard, 4 3/8" 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 3/8" tubing)	7314D-603
1200 ml Reusable Container (external bacteria filter, elbow, 4 3/8" tubing) 6 pk.	7314D-604
External Bacteria Filter (non-sterile), 12 pk. (for reusable container use)	7305D-608
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

Classification (MDD Annex IX):

Ila (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
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.

Validity of this Declaration:

2019-08-07 – 2024-05-26

Somerset, PA,

August 9, 2019

Place, Date

Sandy Figueroa

Sandy Figueroa,
Name and Position

Manager, Regulatory Affairs

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 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 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