

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 to present



Somerset, PA, 20 June 2024

Place

Date

Zita A. Yurko, RAC
Sr. Director Regulatory Affairs
Name and Position

Applied Standards:

7310 series
IEC 60601–1–1:2000 Medical Electrical Equipment—Part 1: General Requirements for Safety; Safety Requirements for Medical Electrical Systems
IEC 60601–1–2, Second Edition, 2001 Medical Electrical Equipment—Part 1: General Requirements for Safety; Electromagnetic Compatibility Requirements and Tests
ISO 14971:2000, Medical devices - Application of risk management to medical devices
EN 55011:1998 Industrial, scientific and medical (ISM) radio-frequency equipment - Radio disturbance characteristics - Limits and methods of measurement Amendment A1:1999 to EN 55011:1998
IEC 529 (1989): Classification of Degrees of Protection Provided by Enclosures
IEC 68 (1988): Environmental Testing – Unit shock and vibration
EN60601-1 current revision plus national deviations
ISO 10079-1:1999 current revision
ISTA Project 3A Test Procedure for testing packaged products