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.: *7310PR-D, 7310PR-I, 7310PR-S, 7310PD-S, 7310PD-PS*

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*
300 cc Single Use Canister, 10 pk.	*7310D-630*
300 cc Single Use Canister, single pk.	*7310D-631*
Battery, replacement, 1 ea.	*7310P-601*
Battery Door	*7310P-602*
Carry Case w/Shoulder Strap	*7310P-606*
725 ml Reusable Container Kit (Jar, Lid/Elbow assembly, Filter)	*7310P-603*
External Bacteria Filter (non-sterile), 12 pk. (for reusable container use)	*7305D-608*
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)*

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*

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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:

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