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. Oxygen Concentrators (UMDNS 12-873)

Catalogue nos.:	*306DS*
Description:	*DeVilbiss iGo® Portable Oxygen System*
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.):

DeVilbiss Rechargeable Battery	*306D-413*
AC Adapter	*306DS-651*
DC/DC Auto Supply	*306DS-652*
Compressor Replacement Kit	*306DS-641*
Humidifier Kit (only for use in Continuous Flow mode)	*306DS-627*
Elbow Humidifier Adapter	*444-507*
Deluxe Carry Case, Rolling	*306DS-635*
Air Filter	*306DS-611*
Power Cord, US	*306DS-601*
Power Cord, EU	*306DS-602*
Power Cord, UK	*306DS-603*
Power Cord, AU	*306DS-604*
Power Cord, CN	*306DS-605*
iGo Accessory Bag	*306DS-655*

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: *2008-08-25*

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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.

Validity of this Declaration: *2019-08-07 – 2024-05-26*

Somerset, PA, 14-Feb-2022

Place Date

Roberto Munoz Director, Regulatory Affairs and Audits

Name and Position

Applied Standards:

306DS
AAMI / ISO 14971:2000 Medical devices - Risk management - Part 1: Application of risk analysis
IEC 60601-1(2005) 3rd edition Medical Electrical Equipment-Part 1:General Requirements for Safety
IEC 60601–1–2, 4th Edition, Medical Electrical Equipment—Part 1: General Requirements for Safety; Electromagnetic Compatibility Requirements and Tests
ISO 8359:1996 Oxygen concentrators for medical use -- Safety requirements
ISO 18779:2005 Medical Devices for Conserving Oxygen and Oxygen Mixtures – Particular Requirements
UPS Standard Shipping Test (ISTA-3A)
RTCA/DO-160G section 21, category M - Environmental Conditions and Test Procedures for Airborne Equipment RTCA/DO-160G section 20, Radio Frequency Susceptibility – Radiated only 100 MHz up to 18 GHZ