EG-Zertifikat / *EC-Certificate*

gem. 93/42/EWG Anhang II ohne (4) / *acc. 93/42/EEC Annex II without (4)*

Hiermit wird bescheinigt, dass die Firma / *This certifies, that the company*

DeVilbiss Healthcare LLC
100 De Vilbiss Drive
Somerset, PA 15501
USA

für die Produkte / die Kategorie: Liste der Produkte siehe Anlage 1
for the products / product category: List of products see annex 1

Geräte für die Beatmungstherapie und Zubehör
Respiratory Care Products and Accessories

ein Qualitätssicherungssystem für die Auslegung, die Fertigung und die Endkontrolle der genannten Produkte nach Maßgabe des Anhang II (ohne Abschnitt 4) der Richtlinie 93/42/EWG anwendet. Zusätzlich zur CE-Kennzeichnung muss die Kennummer der Benannten Stelle angebracht werden. Die Gültigkeit dieses Zertifikats beruht auf der Aufrechterhaltung des Qualitätssicherungssystems in Übereinstimmung mit den Anforderungen der Richtlinie und seiner Überwachung durch die Benannte Stelle gem. Anhang II Abschnitt 5. Das Zertifikat ist unter keinen Umständen übertragbar.

has established a quality system for design, production and final testing acc. to the requirements of Annex II (without section 4) of the directive 93/42/EEC. Additional to the CE-marking the notification number of the Notified Body has to be affixed. The validity of this certificate is based on the maintenance of the quality system in accordance with the requirements of the directive and its surveillance by the Notified Body according Annex II section 5. The certificate may not be transferred under any circumstances.

Reg.-Nr. / *Reg.-No.* 44 232 117803
Bericht Nr. / *Report No.* 3524 7341

Gültigkeit / *Validity*
von / *from* 2019-08-07
bis / *until* 2024-05-26
Edition 4

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2019-07-23

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 44 232 117803

Produkte der Klasse IIa *Products of class IIa*	UMDNS
Sauerstoffkonzentratoren und Zubehör *Oxygen concentrators and accessories*	12-873
CPAP-Beatmungseinheit und Zubehör *Continuous Positive Airway Pressure units and Accessories*	11-001
Sauerstoffversorgungsgerät, kontrolliert und Zubehör *Oxygen Delivery Units, controlled and accessories*	18-076
Absaugkit und Zubehör *Suction Kits and accessories*	13-846
Kompressoren und Zubehör *Compressors and accessories*	10-971
Vernebler und Zubehör *Nebulizers and accessories*	12-712

Bericht Nr. / *Report No.* 3524 7341

Gültigkeit / *Validity*
von / *from* 2019-08-07
Edition 3

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2019-07-23

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

100 DeVilbiss Drive
Somerset, PA 15501
800.338.1988
www.DeVilbissHealthcare.com

13 June 2024

Continued Surveillance - Notified Body Confirmation Letter

Reference: Reg.-Nr 44 232 117803

To whom it may concern,

This letter confirms that, TUV Nord Cert GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0044 on NANDO, was sent a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

DeVilbiss Healthcare, LLC

100 DeVilbiss Drive

Somerset, PA 15501, USA

SRN Number: US-MF-000021684

As required by EU 2023/607 amending regulations EU 2017/745 as regards to the transitional provisions for certain medical devices, the continuous assessment visit was completed by the TUV Nord during the Month of March 2024.

At this time, the formal application for the EU MDR has been lodged with TUV Nord, effective May 26, 2024, along with the written agreement for continuous surveillance pursuant to Art 120(3) of the EU MDR for the devices identified in the Tables below.

- Table 1 identifies the list of devices for which the MDR application was submitted for. TUV Nord only required a representative technical file to be submitted in order to lodge the application. We are attaching the written agreement which is intended to cover the aspects under EU 2023/607. This agreement was signed on 06 Feb 2024.
- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expire after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

Further, in accordance with EU 2023/607, Article 1 – certificates issued by notified bodies in accordance with Directive 92/42/EEC from 25 may 2017, that were still valid on 26 May

100 DeVilbiss Drive
Somerset, PA 15501
800.338.1988
www.DeVilbissHealthcare.com

2021 and that have not been withdrawn afterwards shall remain valid after the end of the period indicated on the certificate until the date set out in paragraph 3a of this regulations for the relevant risk class of the device. This is valid provided the manufacturer and a notified body have a signed a written agreement in accordance with section 4.3 of Annex VII of this regulation for the conformity assessment in response to the expired certificate. The attached written agreement serves to fulfil this requirement under the regulation.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are detailed below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function.
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the company,

Zita Yurko | Sr. Director, Regulatory Affairs

Drive DeVilbiss Healthcare
99 Seaview Blvd

Suite 210
Port Washington, New York 11050

+1 516-760-7712

email. zyurko@drivemedical.com
website. www.drivemedical.com

/attachments: TUV Nord Continuous surveillance contract under EU 2023/607

Complete_with_Doc
uSign_P11F014e_R0(

100 DeVilbiss Drive
Somerset, PA 15501
800.338.1988
www.DeVilbissHealthcare.com

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
1885304SUCTION73UZ	Class IIa – suction Famly	N/A	N/A
1885304OXYDEL35DE	Class IIia – Ifill Family	N/A	N/A
1885304OXYCON25JJ	Class II – stationary Oxygen concentrator Family	N/A	N/A
1885304OXYCON25U	Class II – Portable Oxygen concentrator Family	N/A	N/A

Note: EU 2023/607 continued surveillance permits the extension of the MDD certification under Art 120(3) provided no significant changes are made to any of these devices.

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A