DEHAS Medical Systems GmbH
Wesloer Straße 112
23568 Lübeck
Germany

Confirmation letter correcting and complementing information on an existing certificate in accordance with Article 120 (3) of Regulation (EU) 2017/745

Directive and annex	**Directive 93/42/EEC, Annex II**
Organisation	**DEHAS Medical Systems GmbH**
Registered place of business	Wesloer Straße 112 23568 Lübeck Germany
Certificate number	4153DE410200327 4153GB410200327
Certificate expiry date	2024.05.27
Scope of certification	Central gas supply tubes Pressure regulators Demand valves Mobile gas supply units for liquid and gaseous condition of aggregation Blenders for oxygen mixtures Oxygen monitors for gas mixtures with oxygen
Description of change(s)	change of company name
Effective date of change(s)	2022.08.09

MEDCERT
Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2
20355 Hamburg
e-mail: info@medcert.de· www.medcert.de

Tel.: +49 40 2263325-0
Fax: +49 40 2263325-15
Geschäftsführer: Klaus Dieter Ziel, Dipl.-Ing.
Handelsregister: Hamburg HRB 55912
Steuernummer 48/724/00449
Ust-Identnummer: DE164312394

Bankverbindung:
Deutsche Bank – Konto-Nr.: 27 780 90 - BLZ 200 700 00
IBAN: DE58200700000277809000 - BIC: DEUTDEHHXXX
Hamburger Sparkasse - Konto-Nr.: 1382 120 788 - BLZ 200 505 50
IBAN: DE13200505501382120788 - BIC: HASPDEHHXXX

To whom it may concern,

MEDCERT Prüfungs- und Zertifizierungsgesellschaft für die Medizin GmbH, a Notified Body according to Regulation (EU) 2017/745 on medical devices (MDR)[1] (NB 0482), herewith declares that, pursuant to Article 120 (1) of MDR, since 26 May 2021, no certificate under the Directive 93/42/EEC (Medical Device Directive, or MDD)[2] is allowed to be issued any more. Consequently, pursuant to guidance MDCG 2020-3[3], this Confirmation Letter is valid together with and complements the above-referenced certificate. We as a Notified Body are continuing to perform the surveillance activities for MDD certificates issued by MEDCERT which are still valid, as laid out in the Article 120 (3) of MDR.

We hereby confirm that the above-referenced certificate has been issued to the above-referenced manufacturer and is still valid with the change described in this letter.

We hereby confirm that the aforementioned change is not considered significant change to the design and/or intended purpose as described in Article 120 (3) of MDR. The evaluation of documents related to the change has been completed and approved.

Hamburg, 2022.08.09

Markus Bianchi
Director Certification Body

[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (http://data.europa.eu/eli/reg/2017/745/2020-04-24).
[2] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (http://data.europa.eu/eli/dir/1993/42/2007-10-11).
[3] MDCG 2020-3 Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD (available on https://ec.europa.eu/health/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en).

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