DEHAS
Medical Systems GmbH

Wesloer Straße 107 - 109
D-23568 Lübeck

Tel.: + 49 451 - 80 90 4 - 0
Fax: + 49 451 - 80 90 4 - 111

info@dehas.de
www.DEHAS.de

Wir sind anerkannter Ausbildungsbetrieb
Zertifiziertes QM-System nach EN ISO 13485
Zertifiziert MDSAP
Zertifizierter BeP

QualityMon O_2

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 in regards to the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and*
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	DEHAS Medical Systems GmbH
Manufacturer address and contact details	Wesloer Str. 107 – 109 23568 Lübeck, Germany
Single Registration Number (SRN) (if available)	DE-MF-000005328

Notified body name (if applicable)	DNV MEDCERT GmbH Pilatuspool 2 20355 Hamburg, Germany
Notified body number (if applicable)	0482
Directive Certificate number(s) to which this confirmation is made (if applicable)	4153GB410200327
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024-05-27
End date of extended validity/transition period	2028-12-31

DEHAS
Medical Systems GmbH

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and*
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

Namely by fulfilling the following conditions:

➢ **Directive Certificate** as listed above

- Directive Certificate covering the listed device(s) was/were issued after 25 May 2017, was valid on 26 May 2021 and has not been withdrawn afterwards.

Choose applicable statements:

☒ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☒ A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

JENS MEINCKE, Quality Manager / Regulatory Affairs Manager

E-Mail: J.Meincke@dehas.de

DEHAS Medical Systems GmbH, Wesloer Str. 107-109, 23568 Lübeck, Germany

Location & Date: Lübeck, 16.04.2024

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

QualityMON O2 Series

Identification of the device(s) (e.g., device name, family/group name device model or catalogue number) Identifikation des/der Gerät(e) (z. B. Gerätename, Familien-/Gruppenname, Gerätemodell oder Katalognummer)	**Directive Certificate number(s) to which this confirmation is made** (if applicable) Nummer(n) des Richtlinienzertifikats an den diese Bestätigung erfolgt (wenn anwendbar)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable) Ursprüngliches Ablaufdatum, wie auf dem/den Richtlinienzertifikat(en) vor der Verlängerung der Gültigkeit angegeben (wenn anwendbar)	**Notified Body name and number that issued the Directive Certificate** (if applicable) Name und Nummer der benannten Stelle, die das Richtlinienzertifikat ausgestellt hat (wenn anwendbar)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable) Name und Nummer der benannten Stelle, bei der der MDR-Antrag eingereicht/der Vertrag unterzeichnet wurde (wenn anwendbar)	**End date of extended validity / transition period** Enddatum der verlängerten Gültigkeit/Übergangsfrist	**Substitute Device(s)** (if applicable) Ersatzgerät(e) (wenn anwendbar)
D-B-O2-M	4153GB410200327	2024-05-27	DNV MEDCERT GmbH Pilatuspool 2 20355 Hamburg Germany	DNV MEDCERT GmbH Pilatuspool 2 20355 Hamburg Germany	2028-12-31	N/A
D-B-O2-M-ST	4153GB410200327	2024-05-27	DNV MEDCERT GmbH Pilatuspool 2 20355 Hamburg Germany	DNV MEDCERT GmbH Pilatuspool 2 20355 Hamburg Germany	2028-12-31	N/A
D-DR-O2-M	4153GB410200327	2024-05-27	DNV MEDCERT GmbH Pilatuspool 2 20355 Hamburg Germany	DNV MEDCERT GmbH Pilatuspool 2 20355 Hamburg Germany	2028-12-31	N/A

D-B-O2-M-GO2	4153GB410200327	2024-05-27	DNV MEDCERT GmbH Pilatuspool 2 20355 Hamburg Germany	DNV MEDCERT GmbH Pilatuspool 2 20355 Hamburg Germany	2028-12-31	N/A
D-B-O2-M-HB	4153GB410200327	2024-05-27	DNV MEDCERT GmbH Pilatuspool 2 20355 Hamburg Germany	DNV MEDCERT GmbH Pilatuspool 2 20355 Hamburg Germany	2028-12-31	N/A
0727804	4153GB410200327	2024-05-27	DNV MEDCERT GmbH Pilatuspool 2 20355 Hamburg Germany	DNV MEDCERT GmbH Pilatuspool 2 20355 Hamburg Germany	2028-12-31	N/A
HL-B-O2-M	4153GB410200327	2024-05-27	DNV MEDCERT GmbH Pilatuspool 2 20355 Hamburg Germany	DNV MEDCERT GmbH Pilatuspool 2 20355 Hamburg Germany	2028-12-31	N/A
HVS-B-O2-M	4153GB410200327	2024-05-27	DNV MEDCERT GmbH Pilatuspool 2 20355 Hamburg Germany	DNV MEDCERT GmbH Pilatuspool 2 20355 Hamburg Germany	2028-12-31	N/A
HVS-B-O2-M-GO2	4153GB410200327	2024-05-27	DNV MEDCERT GmbH Pilatuspool 2 20355 Hamburg Germany	DNV MEDCERT GmbH Pilatuspool 2 20355 Hamburg Germany	2028-12-31	N/A
HVS-B-O2-M-HB	4153GB410200327	2024-05-27	DNV MEDCERT GmbH Pilatuspool 2 20355 Hamburg Germany	DNV MEDCERT GmbH Pilatuspool 2 20355 Hamburg Germany	2028-12-31	N/A

HVS-B-O2-M-HB-ST	4153GB410200327	2024-05-27	DNV MEDCERT GmbH Pilatuspool 2 20355 Hamburg Germany	DNV MEDCERT GmbH Pilatuspool 2 20355 Hamburg Germany	2028-12-31	N/A
T-B-O2-M-ST	4153GB410200327	2024-05-27	DNV MEDCERT GmbH Pilatuspool 2 20355 Hamburg Germany	DNV MEDCERT GmbH Pilatuspool 2 20355 Hamburg Germany	2028-12-31	N/A
T-B-O2-M	4153GB410200327	2024-05-27	DNV MEDCERT GmbH Pilatuspool 2 20355 Hamburg Germany	DNV MEDCERT GmbH Pilatuspool 2 20355 Hamburg Germany	2028-12-31	N/A
T-B-O2-M-GO2	4153GB410200327	2024-05-27	DNV MEDCERT GmbH Pilatuspool 2 20355 Hamburg Germany	DNV MEDCERT GmbH Pilatuspool 2 20355 Hamburg Germany	2028-12-31	N/A