Kröber
MEDIZINTECHNIK

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards 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)
- 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	Kröber Medizintechnik GmbH
Manufacturer address and contact details	Salzheck 4 56332 Dieblich
Single Registration Number (SRN) (if available)	DE-MF-000019597
Notified body name (if applicable)	TÜV Rheinland LGA Products GmbH □ See attached schedule
Notified body number (if applicable)	CE 0197 □ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	HD 162605-1 □ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024-05-26 □ See attached schedule
End date of extended validity/transition period	2028-12-31 □ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and
- the listed **devices** 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 or in the attached schedule

- Directive Certificate covering the listed devices was issued after 25 May 2017, was valid on 26 May 2021 and have not been withdrawn afterwards.

X Expires after 20 March 2023:

X Formal applications to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment have been made for the devices listed in the attached schedule and signed written agreements will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

➢ **Quality Management System (QMS)**

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

➢ **Devices as listed in the attached schedule**

- The devices continue to comply with the MDD.
- There are no significant changes in the design and intended purpose.
- The devices 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.

During this period, Declarations of Conformity with Council Directive 93/42/EEC will be issued accordingly.

Signed for and on behalf of the manufacturer:

Kröber Medizintechnik GmbH

Dieblich, Germany 09.04.2024

Dirk Westhues, Managing Director

Contact Details: dwesthues@kroeber.de

Kröber
MEDIZINTECHNIK

Schedule of Devices

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

Identification of the device(s)	Directive Certificate number(s) to which this confirmation is made	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the MDR application was lodged/contract signed	End date of extended validity / transition period
Oxygen Concentrator Kröber O2	HD 162605-1	2024-05-26	TÜV Rheinland LGA Products GmbH CE 0197	TÜV Rheinland LGA Products GmbH CE 0197	2028-12-31
Oxygen concentrator Kröber O2 Vers. 4.0					

Dieblich, Germany 09.04.2024

Kröber Medizintechnik GmbH
Salzheck 4
D- 56332 Dieblich Germany
HRB 5076

Tel.: +49(0)2607 / 9 40 40
Fax: +49(0)2607 / 9 40 422
info@kroeber.de
www.kroeber.de

Geschäftsführung:
Horst Kröber, Dirk Westhues
VAT DE 174 941 975
IK: 590 710 511

Volksbank RheinAhrEifel eG
IBAN: DE06 5776 1591 8146 0112 00
BIC: GENODED1BNA

Sparkasse Koblenz
IBAN: DE52 5705 0120 0013 0020 01
BIC: MALADE51KOB

BPR Medical Ltd.
Hamilton Way, 22
Mansfield, NG18 5BU
UK

02/05/2023

Confirmation Letter Reference: CLNB1639 GBPC228381

To whom it may concern,

Confirmation of receipt of a formal application and conclusion of written agreement in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 on NANDO, has received 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:

BPR Medical Ltd.
Hamilton Way, 22
Mansfield, NG18 5BU
UK
SRN: GB-MF-000003347

Authorised Represantative
Qarad EC-REP BV
Pas 257, 2440 Geel,
Belgium
SRN: BE-AR-000000040

The devices covered by the formal application and the written agreement mentioned above are shown at the end of this letter.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 15 March 2023, this letter also confirms that:

- the manufacturer submitted the MDR application and signed the written agreement by the date of MDD/AIMDD certificate expiry;
- the certificates expired after 26 May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

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 120.3 of MDR (as amended by EU 2023/607), are shown 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 Notified Body SGS Belgium NV 1639,

Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone : +41 22 739 98 58

Devices covered by this letter:

Device name / 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
-Firesafe Cannula Valves and Nozzles for Oxygen therapy circuits for patient protection from fire hazards, 50602745000667 **-Demand Valves for oxygen and analgesic gases,** 5060274500096D	Class IIa	N/A	GB19/964430; NB1639

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/05/02	Version 1	Initial issue