MIETHKE

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 90/385/EEC on Active Implantable Medical Devices (AIMDD) or 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	Christoph Miethke GmbH & Co. KG
Manufacturer address and contact details	Ulanenweg 2 14469 Potsdam, Germany
Single Registration Number (SRN)	DE-MF-000010822
Notified body name	DQS Medizinprodukte GmbH
Notified body number	0297
Directive Certificate number(s) to which this confirmation is made	No. 009066 MR2 ID 170776144 No. 009066 MRA ID 170767825 No. 548597 MRA ID 170770153 No. 549528 MRA ID 170776145
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	2024-05-26
End date of extended validity/transition period	See attached schedule

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Certificate covering the listed devices was issued after 25 May 2017, was valid on 26 May 2021 and has not been withdrawn afterwards.

- Expires *after* 20 March 2023 (2024-05-26)
- Formal applications to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made

➢ Quality Management System (QMS)

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

➢ 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.

Schedule of Devices
This Manufacturer's Declaration is valid for the following devices:

Identification of the devices Device Family	Original expiry date as indicated on the Directive Certificate	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
TD 01 Shunt systems	2024-05-26	DQS Medizinprodukte GmbH (0297)	DQS Medizinprodukte GmbH (0297)	2027-12-31
TD 02 Shunt system accessories	2024-05-26	DQS Medizinprodukte GmbH (0297)	DQS Medizinprodukte GmbH (0297)	2027-12-31
TD 03 Shunt system accessories	2024-05-26	DQS Medizinprodukte GmbH (0297)	DQS Medizinprodukte GmbH (0297)	2027-12-31
TD 04 Instruments Check Mate	2024-05-26	DQS Medizinprodukte GmbH (0297)	DQS Medizinprodukte GmbH (0297)	2028-12-31
TD 05 Instruments THOMALE GUIDE	2024-05-26	DQS Medizinprodukte GmbH (0297)	DQS Medizinprodukte GmbH (0297)	2028-12-31
TD 05 Instruments THOMALE GUIDE Application	2024-05-26	DQS Medizinprodukte GmbH (0297)	DQS Medizinprodukte GmbH (0297)	2028-12-31
TD 06 Instruments Tunneller	2024-05-26	DQS Medizinprodukte GmbH (0297)	DQS Medizinprodukte GmbH (0297)	2028-12-31
TD 07 Shunt Systems with XABO Catheters	2024-05-26	DQS Medizinprodukte GmbH (0297)	DQS Medizinprodukte GmbH (0297)	2027-12-31

Signed for and on behalf of the manufacturer

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Vice President Quality Management and PRRC

Dipl.-Ing. Jörg Knebel

Potsdam, 2024-05-08