



# EU Quality Management Certificate



This is to certify that the company

## Christoph Miethke GmbH & Co. KG

Ulanenweg 2  
14469 Potsdam  
Germany

SRN: DE-MF-000010822

has established, implemented and maintains a Quality Management System in accordance with

### **Annex IX, Chapter I and III of the Regulation (EU) 2017/745 Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation**

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3. Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

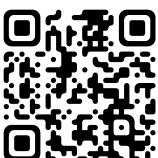
For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	009066 MDR2017Q
Certificate ID	1000306936
Effective date	2026-04-23
Expiry date	2027-03-02
Frankfurt am Main,	2026-04-23



## DQS Medizinprodukte GmbH

Heinrich von Mettenheim  
Managing Director



Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main  
**DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.**  
The validity of the certification can only be verified by the QR-code.



**Annex to EU Quality Management Certificate**  
**SRN of Manufacturer: DE-MF-000010822**  
**Certificate ID: 1000306936**

**Device categories and variants covered by this certificate according to Article 52:**

Device category: **MDA 0101/A - Active implantable devices for cardiovascular/vascular stimulation / inhibition / monitoring**  
Product name: M.scio  
Risk classification: III  
Basic-UDI-DI: 404190600000000000000002RY  
Intended purpose: The M.scio system is used for diagnostic intracranial pressure measurement within the cerebrospinal fluid. Due to the silicone membrane, the dome variants of the system component M.scio have the pumpability and puncturability of a conventional reservoir, i.e. they offer the possibility of therapeutic pressure reduction by removing cerebrospinal fluid, diagnostic removal of cerebrospinal fluid, administration of fluids and verification of the pressure values.

Device category: **MDA 0101/A - Active implantable devices for cardiovascular/vascular stimulation / inhibition / monitoring**  
Product name: SD Card  
Risk classification: III  
Basic-UDI-DI: 404190600000000000000002RY  
Intended purpose: The M.scio system is used for diagnostic intracranial pressure measurement within the cerebrospinal fluid. Due to the silicone membrane, the dome variants of the system component M.scio have the pumpability and puncturability of a conventional reservoir, i.e. they offer the possibility of therapeutic pressure reduction by removing cerebrospinal fluid, diagnostic removal of cerebrospinal fluid, administration of fluids and verification of the pressure values.

Device category: **MDA 0101/A - Active implantable devices for cardiovascular/vascular stimulation / inhibition / monitoring**  
Product name: Reader Unit Set  
Risk classification: III  
Basic-UDI-DI: 404190600000000000000001RW  
Intended purpose: The M.scio system is used for diagnostic intracranial pressure measurement within the cerebrospinal fluid. Due to the silicone membrane, the dome variants of the system component M.scio have the pumpability and puncturability of a conventional reservoir, i.e. they offer the possibility of therapeutic pressure reduction by removing cerebrospinal fluid, diagnostic removal of cerebrospinal fluid, administration of fluids and verification of the pressure values.

Device category: **MDN 1104 - Non-active soft tissue and other implants**  
Product name: MIETHKE Shunt System  
Risk classification: III  
Basic-UDI-DI: 4041906653-MSHUNTS-0002CM  
Intended purpose: The product is intended for shunting of cerebrospinal fluid (CSF).

Device category: **MDN 1104 - Non-active soft tissue and other implants**  
Product name: MIETHKE XABO Shunt System  
Risk classification: III  
Basic-UDI-DI: 4041906555-XABO-0000002CM  
Intended purpose: The product is intended for shunting of cerebrospinal fluid (CSF).



## Annex to EU Quality Management Certificate SRN of Manufacturer: DE-MF-000010822 Certificate ID: 1000306936

Device category: **MDA 0101/A - Active implantable devices for cardiovascular/vascular stimulation / inhibition / monitoring**  
Product name: MIETHKE M.scio Shunt System  
Risk classification: III  
Basic-UDI-DI: 4041906901-MSCIO-IM-010CM  
Intended purpose: The M.scio system is intended for continuous, diagnostic intracranial pressure (ICP) monitoring of cerebrospinal fluid (CSF).

The M.scio implant is an implantable medical device connected to the ventricular catheter for intracranial pressure monitoring and may be integrated into a therapeutic cerebrospinal fluid shunt system.

The implant variants M.scio, dome have the pumpability and puncturability of a conventional reservoir due to the silicone membrane, i.e. they offer the possibility of therapeutic pressure relief by sampling cerebrospinal fluid, diagnostic sampling of cerebrospinal fluid, and verification of pressure values.

Device category: **MDA 0203 - Active non-implantable devices for monitoring of vital physiological parameters**  
Product name: MIETHKE M.scio Shunt System  
Risk classification: III  
Basic-UDI-DI: 4041906612-MSCIO-EX-010CM  
Intended purpose: The M.scio system is intended for continuous, diagnostic intracranial pressure (ICP) monitoring of cerebrospinal fluid (CSF).

The M.scio implant is an implantable medical device connected to the ventricular catheter for intracranial pressure monitoring and may be integrated into a therapeutic cerebrospinal fluid shunt system.

The implant variants M.scio, dome have the pumpability and puncturability of a conventional reservoir due to the silicone membrane, i.e. they offer the possibility of therapeutic pressure relief by sampling cerebrospinal fluid, diagnostic sampling of cerebrospinal fluid, and verification of pressure values.

Device category: **MDN 1208 - Non-active non-implantable instruments**  
Product name: Tunneller  
Risk classification: IIa  
Basic-UDI-DI: 4041906042-TUNNELLER-12CM  
Intended purpose: The Tunneller is a surgical instrument that is used to create a subcutaneous tunnel in which a Shunt System or shunt components are placed to shunt cerebrospinal fluid (CSF).

### Examinations and tests performed:

009066\_MDRReport\_A208388MED\_01 dated 2022-02-08

009066\_A212147MED\_01 dated 2024-08-04

009066\_A214298MED MIETHKE XABO Shunt System dated 2025-06-27

009066\_A217063MED\_MIETHKE M.scio Shunt System dated 2025-12-05

009066\_A214546MED\_dated 2026-02-27



**Annex to EU Quality Management Certificate**  
**SRN of Manufacturer: DE-MF-000010822**  
**Certificate ID: 1000306936**

**Further conditions for or limitations to the validity of the certificate:**  
n/a

**Reference to previous certificates:**

<b>Revision</b>	<b>Date of Issue</b>	<b>Certificate-ID</b>	<b>Description of change</b>
01	2022-03-03	170776551	Initial certification of Miethke Shunt System
02	2024-08-29	1000193466	Addition of the product "MIETHKE XABO Shunt System"
03	2025-08-01	1000258406	Addition of the product "MIETHKE M.scio Shunt System"
04	2026-01-15	1000278341	Addition of the product „Tunneler“