EU-Quality Management Certificate

This is to certify that the company

Christoph Miethke GmbH & Co. KG

Ulanenweg 2
14469 Potsdam
Germany

has implemented a complete Quality Management System for each phase from Design to Final Testing of the products.

Through an audit, documented in a report, carried out by DQS Medizinprodukte GmbH, the proof was provided that this quality management system meets the requirements according to

Annex IX of the Regulation (EU) 2017/745

CONFORMITY ASSESSMENT PROCEDURE ON THE BASIS OF A QUALITY MANAGEMENT SYSTEM AND AN ASSESSMENT OF THE TECHNICAL DOCUMENTATION

regarding the medical devices listed in the Annex:
The manufacturer shall be subject to surveillance in accordance with Annex IX, Chapter 1, Section 3.
The CE marking with the identification number of the Notified Body (0297) may be affixed on the devised listed on the certificate.

In case of devices placed on the market in sterile condition, devices with a measuring function or for devices which are reusable surgical instruments, the involvement of the Notified Body in these procedures shall be limited: in case of products that are placed on the market in sterile condition, limited to the aspects of manufacture concerned with securing and maintaining sterile condition; in the case of devices with a measuring function limited to the aspects related to the conformity of the devices with the metrological requirements; in the case of reusable surgical instruments limited to the aspects related to reuse, in particular cleaning, disinfection, sterilisation, maintenance and functional testing, as well as the related instructions for use.

Certificate registration no.	DE-MF-000010822
Certificate ID	170776551
Previous certificate-ID	n/a
Effective date	2022-03-03
Expiry date	2027-03-02
Frankfurt am Main,	2022-03-03

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

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DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.

420.90 Version 1.0

Annex to EU Quality Management Certificate
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Product name	Risk class	Intended Use
M.scio	Class III	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.
SD Card	Class III	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.
Reader Unit Set	Class III	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.

Examinations and tests performed (e.g. Reference to relevant CS, harmonised standards, test reports and audit report):
009066_MDRReport_A208388MED_01 dated 2022-02-08

Reference to the relevant parts of the technical documentation or other certificates required for the placing on the market of the device or devices covered:
n/a