EU Quality Management Certificate

This is to certify that the company

inomed Medizintechnik GmbH

Im Hausgrün 29
79312 Emmendingen
Germany

SRN: DE-MF-000005589

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.

For placing of devices of class IIa, IIb or III listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	055435 MDR2017Q
Certificate ID	170776510
Effective date	2023-02-23
Expiry date	2028-02-22
Frankfurt am Main,	2023-02-23

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

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Michael Bothe
Head of Certification Body
(active medical devices)

Szymon Kurdyn
Head of Certification Body
(non-active medical devices)

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 this certificate can only be verified by the QR-code.

420.90 Version 5.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000005589
Certificate ID: 170776510

Device categories covered by this certificate:

Device category:	**Stimulation probe with suction function**
Risk classification:	III
Intended purpose:	"The Mapping Suction Probe is a surgical instrument that allows the surgeon to remove secretions and test surgical tissue with nerve stimulation simultaneously and with the same instrument."

Examinations and tests performed:
055435_A208047MED_01 dated 2021-11-05

Further conditions for or limitations to the validity of the certificate:
The manufacturer's quality management system is subject to periodic surveillance in accordance with Annex IX, Chapter 1, Section 3. For placing class III medical devices listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
n/a	n/a	n/a	n/a