



EU Quality Management Certificate



This is to certify that the company

Neuro Enterprises, LLC

11 E. Walton Street 3401
Chicago, IL 60611
United States of America

SRN: US-MF-000036546

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.	551399 MDR2017Q
Certificate ID	1000119691
Effective date	2025-09-04
Expiry date	2030-09-03
Frankfurt am Main,	2025-09-04



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: US-MF-000036546
Certificate ID: 1000119691

Authorised Representative of the company:

MedNet EC-REP GmbH

Borkstraße 10
48163 Münster
Germany

SRN: DE-AR-000000002

Device categories and variants covered by this certificate:

Device category:	MDN1208 - Non-active non-implantable instruments
Product name:	Chicago Tip Suction Instrument
Risk classification:	Class IIa
Basic-UDI-DI:	08600060177ChicagoTip36
Intended purpose:	The Chicago Tip is used to remove fluids and waste from surgical sites. It is intended to be used with commercially available surgical suction systems with standard 1/4-inch tubing.

Examinations and tests performed:

551399_ A212539MED_01 dated 2023-12-19
551399_ A212550MED_02 "Chicago Tip Suction Instrument" dated 2025-07-14

Further conditions for or limitations to the validity of the certificate:

n/a

Reference to previous certificates:

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