EU Quality Management Certificate

This is to certify that the company

evonos GmbH & Co. KG

Stockacher Str. 134
78532 Tuttlingen
Germany

SRN: DE-MF-000005843

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.	495949 MDR2017Q
Certificate ID	1000140210
Effective date	2025-04-25
Expiry date	2030-04-24
Frankfurt am Main,	2025-04-25

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

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.

420.90 Version 7.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000005843
Certificate ID: 1000140210

Device categories and variants covered by this certificate:

Device category:	**MDN 1208 Non-active non-implantable instruments**
Product name:	Cranial Perforators
Risk classification:	IIa
Basic-UDI-DI:	4054462Perforator-Kran7U
Intended purpose:	Cranial perforators are single-use surgical devices for cranial perforation. The perforators with the 3mm step automatically release and stop perforating at a cranial bone thickness of at least 3mm. The perforators with the 1mm step automatically release and stop perforating at a cranial bone thickness of at least 1mm.

Device category:	**MDN 1208 Non-active non-implantable instruments**
Product name:	Screwdriver
Risk classification:	IIa
Basic-UDI-DI:	4054462SD-Single-Use48
Intended purpose:	The screwdriver is a single-use, manual tool intended to apply rotation to tighten/loosen/remove implant screws of the cranial fixation system during neurosurgical procedures.

Device category:	**MDN 1208 Non-active non-implantable instruments**
Product name:	Retractors
Risk classification:	IIa
Basic-UDI-DI:	4054462RetractorLT
Intended purpose:	Retractors are instruments intended to separate the edges of an incision/wound or to hold back various anatomical structures during surgical procedures.

Device category:	**MDN 1208 Non-active non-implantable instruments**
Product name:	Self-Retaining Retractor System
Risk classification:	IIa
Basic-UDI-DI:	4054462Retractor-steril4F
Intended purpose:	The self-retaining retractor system is intended to retract tissue during surgical procedures, to aid in visualisation of and access to the surgical site.

Device category:	**MDN 1208 Non-active non-implantable instruments**
Product name:	Suction and Irrigation Instruments, Cannulas
Risk classification:	IIa
Basic-UDI-DI:	4054462CannulaR2 4054462Cannula-sterilUU
Intended purpose:	Suction cannulas are intended for aspirating blood and other fluids away from the surgical site during surgical procedures. They are designed for connection to active devices but are guided and operated manually.

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Device category:	**MDN 1208 Non-active non-implantable instruments**
Product name:	Suction and Irrigation Instruments, Tubes
Risk classification:	IIa
Basic-UDI-DI:	4054462TubeAY 4054462Tube-sterilJV
Intended purpose:	Suction tubes are intended for aspirating blood and other fluids away from the surgical site during surgical procedures. They are designed for connection to active devices but are guided and operated manually.

Device category:	**MDN 1208 Non-active non-implantable instruments**
Product name:	Suction and Irrigation Instruments, Forceps
Risk classification:	IIa
Basic-UDI-DI:	4054462ForcepsWA
Intended purpose:	Suction forceps and bone punches are intended for holding and cutting tissue as well as aspirating blood and other fluids away from the surgical site during surgical procedures. They are designed for connection to active devices but are guided and operated manually.

Device category:	**MDN 1208 Non-active non-implantable instruments**
Product name:	Suction and Irrigation Instruments, Adapters
Risk classification:	IIa
Basic-UDI-DI:	4054462AdaptorNC
Intended purpose:	Suction adapters are intended for use as a connecting element between suction devices and tubes.

Device category:	**MDN 1208 Non-active non-implantable instruments**
Product name:	Suction and Irrigation Instruments, Elevators
Risk classification:	IIa
Basic-UDI-DI:	4054462ElevatorHJ
Intended purpose:	Suction elevators are intended for scraping, elevating or dissecting bone or tissue as well as aspirating blood and other fluids away from the surgical site during surgical procedures. They are designed for connection to active devices but are guided and operated manually.

Device category:	**MDN 1208 Non-active non-implantable instruments**
Product name:	Suction and Irrigation Instruments, Protectors
Risk classification:	IIa
Basic-UDI-DI:	4054462Guard9E
Intended purpose:	Suction protectors are intended for aspirating blood and other fluids away from the surgical site during surgical procedures. They have guards that are designed to protect patients and/or instruments.

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Device category:	**MDN 1208 Non-active non-implantable instruments**
Product name:	Scalp Clips
Risk classification:	IIa
Basic-UDI-DI:	4054462Clip-sterileR4
Intended purpose:	Scalp clips are intended to provide haemostasis to scalp flap edges during neurosurgical procedures. They are designed to be attached to the edges of scalp tissue to prevent bleeding.

Device category:	**MDN 1208 Non-active non-implantable instruments**
Product name:	Skull Pins
Risk classification:	IIa
Basic-UDI-DI:	4054462Pins-sterileBZ 4054462Pins-unsterileEE
Intended purpose:	Skull pins are intended for use with a headrest system to clamp the patient's skull and hold the head and neck in a particular position during surgical procedures.

Examinations and tests performed:
495949_A213549MED_01 dated 2024-06-13
495949_A212513MED_02 Cranial Perforator EVODRILL dated 2025-04-14

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