EU Quality Management Certificate

This is to certify that the company

Sutter Medizintechnik GmbH

Alfred-Walz-Straße 22
79312 Emmendingen
Germany

SRN: DE-MF-000005544

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.	005332 MDR2017Q
Certificate ID	1000169465
Effective date	2024-07-24
Expiry date	2028-01-11
Frankfurt am Main,	2024-07-24

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 6.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000005544
Certificate ID: 1000169465

Device categories and variants covered by this certificate:

Device category:	**MDA 0312 - Other active non-implantable surgical devices**
Product name:	Bipolar forceps
Risk classification:	IIb
Basic-UDI-DI:	++ESUMTD02700000AL
Intended purpose:	Electrosurgical coagulation of selected tissue. If suction channel available, also suction of liquids. If irrigation channel available, also liquid supply.

Device category:	**MDA 0312 - Other active non-implantable surgical devices**
Product name:	Bipolar clamps
Risk classification:	IIb
Basic-UDI-DI:	++ESUMTD117009006C3
Intended purpose:	Electrosurgical coagulation of soft tissue. If suction channel available, also suction of liquids.

Examinations and tests performed:
005332_A209185MED_01 dated 2022-05-13
005332_A209185MED_02 dated 2023-01-10

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
01	2023-01-12	170777376	Change of device category
02	2023-10-02	1000134799	Change the certificate template