EU Technical Documentation Assessment Certificate

This is to certify that the company

Sutter Medizintechnik GmbH

Alfred-Walz-Straße 22
79312 Emmendingen
Germany

SRN: DE-MF-000005544

has established and maintains the required Technical Documentation in accordance with

Annex IX, Chapter II 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 Technical Documentation has been verified and confirmed in Conformity Assessment Procedures according to Article 52. The Technical Documentation is subject to regular surveillance. Limitations to this certificate are listed in the Annex.

For placing devices listed in the Annex on the market, an additional certificate according to Annex IX, Chapter I and III is required.

Devices of class IIa and IIb listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

Certificate registration no.	005332 MDR2017B
Certificate ID	1000134798
Effective date	2023-10-02
Expiry date	2028-01-11
Frankfurt am Main,	2023-10-02

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.

420.91 Version 5.0

Annex to EU Technical Documentation Assessment Certificate
SRN of Manufacturer: DE-MF-000005544
Certificate ID: 1000134798

Device categories and variants covered by this certificate:

Device category:	**Open electrosurgery forceps, reusable**
Product name:	Bipolar forceps
Models:	n/a
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:	**Open electrosurgery forceps, reusable**
Product name:	Bipolar clamps
Models:	n/a
Risk classification:	IIb
Basic-UDI-DI:	++ESUMTD11700900c3
Intended purpose:	Electrosurgical coagulation on soft tissue. If suction channel available, also suction of liquids.

Examinations and tests performed:
005332_A209185MED_02 dated 2023-01-10

Further conditions for or limitations to the validity of the certificate:
Products listed on the certificate may bear the CE marking with the identification number of the Notified Body (0297).

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2023-01-12	170777377	Change of device category