EU Quality Management Certificate

This is to certify that the company

Storz am Mark GmbH

Emminger Straße 39
78576 Emmingen-Liptingen
Germany

SRN: SRN: DE-MF-000005320

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.	073007 MDR2017Q
Certificate ID	1000173600
Effective date	2024-04-12
Expiry date	2029-04-11
Frankfurt am Main,	2024-04-12

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: SRN: DE-MF-000005320
Certificate ID: 1000173600

Device categories and variants covered by this certificate:

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Cutting-scraping medical devices
Risk classification:	Class I (reprocessable)
Basic-UDI-DI:	ESAM05697
Intended purpose:	Surgical hand instruments for tissue manipulation with the functions of cutting, severing, blunt dissection, ablation and compression of tissue or other materials. As a rule tissue parts such as soft tissue, bone material, cartilage, dentine or other types of tissue or separable material. types of tissue or separable material. Surgically invasive, reusable products for temporary use

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	rasping-clamping medical devices
Risk classification:	Class I (reprocessable)
Basic-UDI-DI:	ESAM06496
Intended purpose:	Surgical hand instruments for tissue manipulation with the functions of gripping and holding tissue with and without locking function as well as holding needles, swabs and other auxiliary materials for surgical interventions. Surgically invasive, reusable products for temporary use.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Auxiliary products
Risk classification:	Class I (reprocessable)
Basic-UDI-DI:	ESAM0068Q
Intended purpose:	Surgical hand instruments and products that are used for processing tissue samples outside the body or serve as assistance instruments

Examinations and tests performed:
073007_ A211569MED_01 dated 2023-01-27
073007_ A211569MED_02 rasping-clamping medical devices dated 2024-04-10

Further conditions for or limitations to the validity of the certificate:
For reusable surgical instruments, the involvement of the notified body in the conformity assessment procedure is limited to the aspects related to reuse, in particular cleaning, disinfection, sterilisation, maintenance and functional testing and the associated instructions for use.

Reference to previous certificates:

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