EU Quality Management Certificate

This is to certify that the company

Storz am Mark GmbH

Emminger Straße 39
78576 Emmingen-Liptingen
Germany

SRN: DE-MF-000005620

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	1000276939
Effective date	2025-12-10
Expiry date	2029-04-11
Frankfurt am Main,	2025-12-10

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-000005620
Certificate ID: 1000276939

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 grasping 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

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Rotating instruments
Risk classification:	Class IIa
Basic-UDI-DI:	++ESAM0508T ++ESAM0528X
Intended purpose:	Reusable rotary Instruments, such as pilot drills, trephine drills, and tissue punches, are used in conjunction with a compatible dental drive system and serve for the cutting or drilling expansion of bone or soft tissue.

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000005620
Certificate ID: 1000276939

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Suction Instruments
Risk classification:	IIa
Basic-UDI-DI:	++ESAM03793
Intended purpose:	The intended use of the suction instruments is the aspiration of secretions, blood, and other fluids, as well as small tissue fragments, from the oral cavity and the surgical area during invasive and surgically invasive procedures. They are designed to be connected to active suction pumps of risk class IIa via a flexible hose connection. They are used by dentists, dental and maxillofacial surgeons, or their assisting personnel during temporary procedures.

Examinations and tests performed:
073007_ A211569MED_01 dated 2023-01-27
073007_ A211569MED_02 rasping-clamping medical devices dated 2024-04-10
073007_A213900MED_03 Rotating Instruments dated 2025-09-12

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
01	2024-04 12	1000173600	Change of SRN number
02	2025-02-20	1000216273	Addition „Rotating Instruments“
03	2025-11-06	1000265840	Addition „Suction Instruments“ and correction of the intended purpose for PHA-03 Rotating Instruments