EU Technical Documentation Assessment Certificate

This is to certify that the company

KARL STORZ SE & Co. KG

Dr.-Karl-Storz-Straße 34
78532 Tuttlingen
Germany

SRN: DE-MF-000005723

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 IIb and III as listed on the certificate may bear the CE marking with the identification number of the Notified Body (0297).

Certificate registration no.	528525 MDR2017P
Certificate ID	170782068
Effective date	2023-02-02
Expiry date	2028-02-01
Frankfurt am Main,	2023-02-02

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.

420.92 Version 5.0

Annex to EU Technical Documentation Assessment Certificate
SRN of Manufacturer: DE-MF-000005723
Certificate ID: 170782068

Device categories and variants covered by this certificate:

Device category:	**Screw**
Product name:	Mega Fix
Models:	2870619B, 2870619C, 2870623B, 2870623C, 2870719B, 2870719C, 2870723B, 2870723C, 2870728B, 2870728C, 2870819B, 2870819C, 2870823B, 2870823C, 2870823CP, 2870823P, 2870828B, 2870828C, 2870828CP, 2870828P, 2870923B, 2870923C, 2870923CP, 2870923P, 2870928B, 2870928C, 2870928CP, 2870928P, 2870935CP, 2870935P, 2871028CP, 2871028P, 2871035CP, 2871035P, 2871135CP, 2871135P
Risk classification:	III
Basic-UDI-DI:	4048551001843UD
Intended purpose:	The bioresorbable implants are used for ligament reconstruction during therapeutic open surgical, arthroscopic, and minimally invasive procedures.

Examinations and tests performed:
528525_A209397MED_01 dated 2022-11-12

Further conditions for or limitations to the validity of the certificate:

Reference to previous certificates:

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