CERTIFICATE

This is to certify that the company

TROKAMED GmbH

Kleine Breite 17
78187 Geisingen
Germany

has implemented and maintains a **Quality Management System**.

Scope:
Design, development, production and distribution of surgical, endoscopic and orthopedic instruments.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

DIN EN ISO 13485 : 2016 + AC : 2017-07
EN ISO 13485 : 2016 + AC : 2016
ISO 13485 : 2016

Certificate registration no.	071052 MP2016
Certificate unique ID	170778642
Effective date	2021-12-20
Expiry date	2024-12-19
Frankfurt am Main	2021-12-20

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16021-01-00

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

TROKAMED GmbH

Kleine Breite 17
78187 Geisingen
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Instruments and Devices for Surgery and Endoscopy according annex

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	071052 MR2
Certificate unique ID	170774582
Effective date	2020-11-27
Expiry date	2024-03-31
Frankfurt am Main	2020-11-27

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

411.20 Version 1.0

Annex to certificate
Certificate registration No.: 071052 MR2
Certificate unique ID: 170774582
Effective date: 2020-11-27

TROKAMED GmbH

Kleine Breite 17
78187 Geisingen
Germany

Device family	Device	Class
Cannula and Needle for Endoscopy	Sheaths for Gynaecology, Sinuscopy, Urology, Arthroscopy, Nephroscopy, Neurosurgery and other Cannulas	IIa
	Suction-Irrigation-Cannula, Trokar Sleeves, Lavage Units, Verres Needle	IIa
Instruments and Devices for Endoscopy	Uterine Manipulator, Elevators, Retractors, Working Element, Fittings/Adapters	IIa
	Electrodes HF, Laparoscopic Forceps and – Scissors, Working Element HF Surgery and Accessories	IIb
	Sterile Electrodes HF	IIb
Operationsunit, motorized	Power Unit with Handle Accessories Cutting Module, steril Valve Module, steril	IIa
Instruments for Orthopedics and Traumatology	Drills and chamfer	IIa

CERTIFICATE

This is to certify that the company

TROKAMED GmbH

Kleine Breite 17
78187 Geisingen
Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope of certification:
Design, development, production and distribution of surgical, endoscopic and orthopedic instruments.
-CND, JPN, USA (a,b,c,d)

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

ISO 13485 : 2016

including applicable country-specific regulatory requirements, as indicated below the scope (full references of abbreviations are listed in the annex)

Certificate registration no.	071052 MDSAP16
Certificate unique ID	170778643
Effective date	2022-01-30
Expiry date	2025-01-29
Frankfurt am Main	2021-12-20

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Szymon Kurdyn
Product Manager

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de
DQS Medizinprodukte GmbH is recognized under the Medical Devices Single Audit Program.
Visit https://www.dqs.de/en/customer-database/ to validate this certificate.

413.01 Version 6.0

Annex to certificate
Certificate registration No.: 071052 MDSAP16
Certificate unique ID: 170778643
Effective date: 2022-01-30

TROKAMED GmbH

Kleine Breite 17
78187 Geisingen
Germany

Audited site	REPs FEI No.: site scope and country-specific requirements
071052 **TROKAMED GmbH** Kleine Breite 17 78187 Geisingen Germany	Design, development, production and distribution of surgical, endoscopic and orthopedic instruments. **-CND, JPN, USA (a,b,c,d)** **REPs FEI No.: F000661**

Annex to certificate
Certificate registration No.: 071052 MDSAP16
Certificate unique ID: 170778643
Effective date: 2022-01-30

TROKAMED GmbH

Kleine Breite 17
78187 Geisingen
Germany

Full references of country-specific requirements of MDSAP participating Regulatory Authorities

Abbreviation	Jurisdiction	Reference
AUS	Australia	(a) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 – Full Quality Assurance Procedure (b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure
BRA	Brazil	RDC ANVISA n. 16/2013 RDC ANVISA n. 23/2012 RDC ANVISA n. 67/2009
CND	Canada	Medical Device Regulations SOR/98-282, Part 1
JPN	Japan	MHLW Ministerial Ordinance No. 169 (2004) as amended by MHLW Ordinance No. 128 (2014), Articles 4 to 68 Japan PMD Act (as applicable)
USA	United States	(a) 21 CFR Part 803 (b) 21 CFR Part 806 (c) 21 CFR Part 807 (d) 21 CFR Part 820 (e) 21 CFR Part 821