EU Quality Management Certificate

This is to certify that the company

EPflex Feinwerktechnik GmbH

Im Schwöllbogen 24
72581 Dettingen/Erms
Germany

SRN: DE-MF-000005425

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. Limitations to this certificate are listed in the Annex.

For placing of devices of class IIa, IIb or III listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	013536 MDR2017Q
Certificate ID	1000145040
Effective date	2023-11-09
Expiry date	2028-11-08
Frankfurt am Main,	2023-11-09

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)

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000005425
Certificate ID: 1000145040

Device categories covered by this certificate:

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Risk classification:	Is
Intended purpose:	Stone Retrieval Devices are intended for the endoscopic removal of stones from the urogenital tract or the common bile duct during retrograde interventions.

Examinations and tests performed:
013536_A211493MED_01 dated 2023-11-03

Further conditions for or limitations to the validity of the certificate:
The manufacturer's quality management system is subject to periodic surveillance in accordance with Annex IX, Chapter 1, Section 3.
In case of products that are placed on the market in sterile condition, the involvement of the Notified Body in the conformity assessment procedure is limited to the aspects of manufacture concerned with securing and maintaining sterile condition.

Reference to previous certificates:

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