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 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.	013536 MDR2017Q
Certificate ID	1000189787
Effective date	2024-08-01
Expiry date	2028-11-08
Frankfurt am Main,	2024-08-01

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 the certification can only be verified by the QR-code.

420.90 Version 6.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000005425
Certificate ID: 1000189787

Device categories and variants covered by this certificate:

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Stone Retrieval Devices
Risk classification:	Is
Basic-UDI-DI:	42556056srd7T
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.

Device category:	**MDN 1203 - Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools**
Product name:	Guidewires for central circulatory application
Risk classification:	III
Basic-UDI-DI:	42556056gwcIIIEH
Intended purpose:	The Guidewires are intended to facilitate the introduction and placement of catheters or other interventional or diagnostic devices within the central circulatory system, the heart chambers and the coronary vasculature during diagnostic or interventional procedures.

Device category:	**MDN 1203 - Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools**
Product name:	Guidewires for peripheral application
Risk classification:	lla
Basic-UDI-DI:	42556056gwcIIaFP
Intended purpose:	The Guidewires are intended to facilitate the introduction and placement of diagnostic or therapeutic devices in peripheral vasculature or hollow organs of the human body during endoscopic or interventional procedures.

Examinations and tests performed:
013536_A211493MED_01 dated 2023-11-03
013536_A211493MED_02 Stone Retrieval Devices 2023-04-17
013536_A211667MED dated 2024-06-24
013536_A211493MED_03 Guidewires for peripheral application dated 2024-07-27

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

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000005425
Certificate ID: 1000189787

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2023-11-09	1000145040	Addition of the Product Guidewire and new revised certificate edition
02	2024-07-03	1000184098	Addition of the Product Guidewires for peripheral application