



CERTIFICATE



This is to certify that the company

EPflex Feinwerktechnik GmbH

Im Schwöllbogen 24
72581 Dettingen/Erms
Germany

with the organizational units/sites as listed in the annex

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

Scope:

Development, production and distribution of non-active, sterile and non-sterile medical devices for invasive and surgical invasive applications of guide wires, baskets, stone grippers, hypotubes, stiletos and minimal invasive flexible 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. 013536 MP2016

Certificate unique ID 170717930

Effective date 2019-03-22

Expiry date 2022-03-21

Frankfurt am Main 2019-03-22



DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body



Annex to certificate
Certificate registration No.: 013536 MP2016
Certificate unique ID: 170717930
Effective date: 2019-03-22

EPflex Feinwerktechnik GmbH

Im Schwöllbogen 24
72581 Dettingen/Erms
Germany

Location

Scope

500629
EPflex Feinwerktechnik GmbH
Zentrale und Produktion
Im Schwöllbogen 24
72581 Dettingen/Erms
Germany

Development, production and distribution of non-active, sterile and non-sterile medical devices for invasive and surgical invasive applications of guide wires, baskets, stone grippers, hypotubes, stiletos and minimal invasive flexible instruments.

500630
EPflex Feinwerktechnik GmbH
Produktion
Vogelsangstraße 60
72581 Dettingen/Erms
Germany

Development, production and distribution of non-active, sterile and non-sterile medical devices for invasive and surgical invasive applications of guide wires, baskets, stone grippers, hypotubes, stiletos and minimal invasive flexible instruments.