# EU Technical Documentation Assessment Certificate

This is to certify that the company

## EPflex Feinwerktechnik GmbH

Im Schwöllbogen 24
72581 Dettingen/Erms
Germany

SRN: DE-MF-000005425

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.

Devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing devices listed in the Annex on the market, an additional certificate according to Annex IX, Chapter I and III is required.

| | |
|---|---|
| Certificate registration no. | 013536 MDR2017P |
| Certificate ID | 1000184097 |
| Effective date | 2024-07-03 |
| Expiry date | 2029-07-02 |
| Frankfurt am Main, | 2024-07-03 |

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

**DQS Medizinprodukte GmbH**

Sigrid Uhlemann
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(active medical devices)

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Head of Certification Body
(non-active medical devices)

# Annex to EU Technical Documentation Assessment Certificate
# SRN of Manufacturer: DE-MF-000005425
# Certificate ID: 1000184097

**Device categories and variants covered by this certificate:**

| | |
|---|---|
| Device category: | **MDN 1203 - Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools** |
| Product name: | Guidewires |
| Models: | n/a |
| 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. |

**Examinations and tests performed:**
013536_A211667MED dated 2024-06-24

**Further conditions for or limitations to the validity of the certificate:**
n/a

**Reference to previous certificates:**

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