# EU Quality Management Certificate

This is to certify that the company

## pro med instruments GmbH

Bötzinger Straße 86
79111 Freiburg
Germany

SRN: DE-MF-000005752

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.

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| Certificate registration no. | 221096 MDR2017Q |
| Certificate ID | 1000178451 |
| Effective date | 2024-05-17 |
| Expiry date | 2028-07-05 |
| Frankfurt am Main, | 2024-05-17 |

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)

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

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 this certificate can only be verified by the QR-code.**



420.90 Version 6.0

# Annex to EU Quality Management Certificate
# SRN of Manufacturer: DE-MF-000005752
# Certificate ID: 1000178451

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|---|---|
| Device category: | **MDN 1208 - Non-active non-implantable instruments** |
| Product name: | DORO® Sterile Disposable Skull Pins |
| Risk classification: | IIa |
| Basic-UDI-DI: | 42504355PA0601YS |
| Intended purpose: | Indicated for use in combination with a skull clamp in open and percutaneous craniotomies as well as spinal surgery when rigid fixation is necessary. |

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| Device category: | **MDN 1208 - Non-active non-implantable instruments** |
| Product name: | DORO® Reusable Skull Pins |
| Risk classification: | IIa |
| Basic-UDI-DI: | 42504355PA0602YU |
| Intended purpose: | Indicated for use in combination with a skull clamp in open and percutaneous craniotomies as well as spinal surgery when rigid fixation is necessary. |

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| Device category: | **MDN 1208 - Non-active non-implantable instruments** |
| Product name: | DORO® Blades |
| Risk classification: | III |
| Basic-UDI-DI: | 42504355PA0801Z4 |
| Intended purpose: | The DORO® Blades are intended to retract tissue, especially brain tissue. During surgical procedures, they keep the operation field open for the surgeon and enable the access to deeper areas within the head of the patient. |

**Examinations and tests performed:**
n/a

**Further conditions for or limitations to the validity of the certificate:**
221096_A208319MED_01 dated 2022-07-24
221096_A208319MED_02 dated 2023-06-08
221096_A208319MED_03 dated 2024-05-03

**Reference to previous certificates:**

| Revision | Date of Issue | Certificate-ID | Description of change |
|---|---|---|---|
| 01 | 2023-07-06 | 170778720 | Addition DORO® Blades |
| 02 | 2024-03-22 | 1000165213 | Extension to product DORO Sterile Disposable Skull Pins |