EU Quality Management Certificate

This is to certify that the company

Black Forest Medical GmbH

Bötzinger Straße 86
79111 Freiburg im Breisgau
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.

Certificate registration no.	221096 MDR2017Q
Certificate ID	1000297665
Effective date	2026-01-29
Expiry date	2028-07-05
Frankfurt am Main,	2026-01-29

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

DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director

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 7.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000005752
Certificate ID: 1000297665

Device categories and variants covered by this certificate:

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.

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.

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:
221096_A208319MED_01 dated 2022-07-24
221096_A208319MED_02 dated 2023-06-08
221096_A208319MED_03 dated 2024-05-03
221096_A208502MED_04 dated 2026-01-16

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	2023-07-06	170778720	Addition DORO® Blades
02	2024-03-22	1000165213	Extension to product DORO Sterile Disposable Skull Pins
03	2024-05-17	1000178451	Change of company name from pro med instruments GmbH to Black Forest Medical GmbH
04	2025-09-18	1000261887	Change notification for the product “DORO® Blades”