



EU Technical Documentation Assessment 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 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. 31621927 MDR2017P

Certificate ID 1000297641

Effective date 2026-01-29

Expiry date 2029-03-21

Frankfurt am Main, 2026-01-29



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

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.



Annex to EU Technical Documentation Assessment Certificate

SRN of Manufacturer: DE-MF-000005752

Certificate ID: 1000297641

Device categories and variants covered by this certificate:

Device category: **MDN 1208 - Non-active non-implantable instruments**
Product name: **DORO® Blades**
Models: **n/a**
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_A208050MED dated 2024-03-14
221096_A218502MED 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	2024-03-22	1000165207	Change of company name from pro med instruments GmbH to Black Forest Medical GmbH
02	2025-09-18	1000262101	Change notification for the product "DORO® Blades"