



# EU Technical Documentation Assessment Certificate

This is to certify that the company

## Black Forest Medical GmbH

Bötzingen 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).

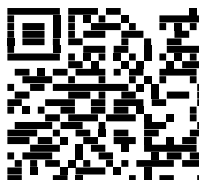
For placing devices listed in the Annex on the market, an additional certificate according to Annex IX, Chapter I and III is required.

Certificate registration no.	31621927 MDR2017P
Certificate ID	1000297641
Effective date	2026-01-29
Expiry date	2029-03-21
Frankfurt am Main,	2026-01-29



## 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:	<b>MDN 1208 - Non-active non-implantable instruments</b>
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"