# EU Technical Documentation Assessment Certificate

This is to certify that the company

## bess pro gmbh

Gustav-Krone-Straße 7
14167 Berlin
Germany

SRN: DE-MF-000006209

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. | 31639420 MDR2017P |
| Certificate ID | 1000333049 |
| Effective date | 2026-11-03 |
| Expiry date | 2031-11-02 |
| Frankfurt am Main, | 2026-11-03 |

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

**DQS Medizinprodukte GmbH**

Sven Hoffmann
Managing Director

# Annex to EU Technical Documentation Assessment Certificate
# SRN of Manufacturer: DE-MF-000006209
# Certificate ID: 1000333049

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

| | |
|---|---|
| Device category: | **MDN 1104 - Non-active soft tissue and other implants** |
| Product name: | bess\|oto |
| Models: | n/a |
| Risk classification: | IIb implant |
| Basic-UDI-DI: | 4063106VETAY |
| Intended purpose: | Temporary ventilation and / or drainage of the tympanic cavity. Placement after paracentesis. |

**Examinations and tests performed:**
533216_A211673MED dated 2026-07-18

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

**Reference to previous certificates:**

| Version | Date of Issue | Certificate-ID | Description of change |
|---|---|---|---|
| 01 | 2026-11-03 | 1000333049 | Initial certificate |