EU Quality Management Certificate

This is to certify that the company

bess pro gmbh

Gustav-Krone-Straße 7
14167 Berlin
Germany

SRN: DE-MF-000006209

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.	532216 MDR2017Q
Certificate ID	170782649
Effective date	2025-02-28
Expiry date	2030-02-27
Frankfurt am Main,	2025-02-28

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-000006209
Certificate ID: 170782649

Device categories and variants covered by this certificate:

Device category:	**MDN 1204 - Non-active non-implantable devices for wound and skin care**
Product name:	bess|folio restricted FOLIOXANE® RESTRICTED
Risk classification:	IIa
Basic-UDI-DI:	4063106FOL8W
Intended purpose:	The product is intended for support and wound care in nasal cavity, auditory canal, tympanic membrane, mouth or skin

Examinations and tests performed:
532216_A211279MED_01 dated 2023-03-17
532216_A211279MED_02 bess|folio restricted dated 2025-02-13

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
n/a	n/a	n/a	n/a