EU Quality Management Certificate

This is to certify that the company

bess pro gmbh

Gustav-Krone-Straße 7
14167 Berlin
Deutschland

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	1000301888
Effective date	2026-07-02
Expiry date	2030-02-27
Frankfurt am Main,	2026-07-02

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 Quality Management Certificate
SRN of Manufacturer: DE-MF-000006209
Certificate ID: 1000301888

Device categories and variants covered by this certificate according to Article 52:

Device category:	**MDN 1204 - Non-active non-implantable devices for wound and skin care**
Product name:	FOLIOXANE RESTRICTED
Risk classification:	IIa
Basic-UDI-DI:	4063108FOLIOXREY8
Intended purpose:	The product is intended for support and wound care in nasal cavity, auditory canal, tympanic membrane, mouth or skin

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

Device category:	**MDN 1104 - Non-active soft tissue and other implants**
Product name:	aerstent / aixstent
Risk classification:	IIb Implant
Basic-UDI-DI:	4063106ASTAERLX 4063106ASTAIXMP
Intended purpose:	The stent is intended to maintain or enable the patency of natural and artificial lumen in the body and/or to cover pathological changes.

Examinations and tests performed:
532216_A211279MED_01 dated 2023-03-17
532216_A211279MED_02 bess|folio restricted dated 2025-02-13
532216_A213903MED_03 aerstent / aixstent dated 2026-04-15

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	2025-02-28	170782649	Addition of the product “aerstent / aixstent” Adjustment of basic UDI-DI Splitting of the products folio and FOLIOXANE