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.	532216 MDR2017P
Certificate ID	1000310118
Effective date	2026-07-02
Expiry date	2031-07-01
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 Technical Documentation Assessment Certificate
SRN of Manufacturer: DE-MF-000006209
Certificate ID: 1000310118

Device categories and variants covered by this certificate:

Device category:	**MDN 1104 – Non-active soft tissue and other implants**
Product name:	aerstent / aixstent
Models:	Aerstent TBS / TBJ; aerstent TBY; aixstent OES / OEC / OEL; aixstent BDS / BDP; aixstent CRE; aixstent DUS; aixstent PPS
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_A213903MED 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
n/a	n/a	n/a	n/a