CERTIFICATE

This is to certify that the company

bess pro gmbh

Gustav-Krone-Straße 7
14167 Berlin
Germany

has implemented and maintains a **Quality Management System**.

Scope of certification:
Development and production of medical devices: implants, single-use medical devices, instruments and accessories in the fields of head & neck surgery / reconstructive and plastic surgery / pulmonology / ophthalmology / gastroenterology / endoscopy.
Pretreatment and filling of powdery medical devices, clean room production including silicone injection molding and contract sterilization.
- AUS, BRA, CND, JPN, USA (a, b, c, d)

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

ISO 13485 : 2016

including applicable country-specific regulatory requirements, as indicated below the scope (full references of abbreviations are listed in the annex)

Certificate registration no.	532216 MDSAP16
Certificate unique ID	1000117229
Effective date	2023-08-21
Expiry date	2026-08-20
Frankfurt am Main	2023-08-11

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Marc Goedecke
Product Manager

Annex to certificate
Certificate registration No.: 532216 MDSAP16
Certificate unique ID: 1000117229
Effective date: 2023-08-21

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Gustav-Krone-Straße 7
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Audited site

532216
bess pro gmbh
Gustav-Krone-Straße 7
14167 Berlin
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REPs FEI No.: site scope and country-specific requirements

Development and production of medical devices: implants, single-use medical devices, instruments and accessories in the fields of head & neck surgery / reconstructive and plastic surgery / pulmonology / ophthalmology / gastroenterology / endoscopy. Pretreatment and filling of powdery medical devices, clean room production including silicone injection molding and contract sterilization.
- AUS, BRA, CND, JPN, USA (a, b, c, d)
REPs FEI No.: F004873

Annex to certificate
Certificate registration No.: 532216 MDSAP16
Certificate unique ID: 1000117229
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Full references of country-specific requirements of MDSAP participating Regulatory Authorities

Abbreviation	Jurisdiction	Reference
AUS	Australia	(a) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 – Full Quality Assurance Procedure (b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure
BRA	Brazil	RDC ANVISA n. 665/2022 RDC ANVISA n. 551/2021 RDC ANVISA n. 67/2009
CND	Canada	Medical Device Regulations SOR/98-282, Part 1
JPN	Japan	MHLW Ministerial Ordinance No. 169 (2004) as amended by MHLW Ordinance No. 128 (2014), Articles 4 to 68 Japan PMD Act (as applicable)
USA	United States	(a) 21 CFR Part 803 (b) 21 CFR Part 806 (c) 21 CFR Part 807 (d) 21 CFR Part 820 (e) 21 CFR Part 821