



# CERTIFICATE



This is to certify that the company

## **bess AG**

Gustav-Krone-Straße 7  
14167 Berlin  
Germany

with the organizational units/sites as listed in the annex

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

### Scope:

Management of centralized services for the bess group companies: research & development, quality management, regulatory affairs, medical affairs, distribution.

Distribution of medical devices: implants (including medical device variants and custom made medical devices), single-use medical devices, instruments and accessories in the fields of ear, nose & throat, head & neck surgery / reconstructive and plastic surgery / thoracic surgery / pulmonology / ophthalmology / gastroenterology / endoscopy / anaesthesia

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:

**DIN EN ISO 13485 : 2016 + AC : 2017-07**

**EN ISO 13485 : 2016 + AC : 2018**

**ISO 13485 : 2016**

Certificate registration no.	532215 MP2016
Certificate unique ID	1000117306
Effective date	2023-10-05
Expiry date	2026-10-04
Frankfurt am Main	2023-08-12



DQS IS A MEMBER OF



## **DQS Medizinprodukte GmbH**

Sigrid Uhlemann  
Managing Director

Szymon Kurdyn  
Product Manager



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The validity of this certificate can only be verified by the QR-code.



**Annex to certificate**  
**Certificate registration No.: 532215 MP2016**  
**Certificate unique ID: 1000117306**  
**Effective date: 2023-10-05**

## **bess AG**

Gustav-Krone-Straße 7  
14167 Berlin  
Germany

### **Location**

### **Scope**

**541926**

**Bess AG**

Gustav-Krone-Straße 7  
14167 Berlin  
Germany

Development, production and distribution of medical devices: implants, single-use medical devices, instruments and accessories, also for third parties.

**533256**

**bess medizintechnik gmbh**

Gustav-Krone-Straße 7  
14167 Berlin  
Germany

Distribution of medical devices: implants (including medical device variants and custom made medical devices), single-use medical devices, instruments and accessories in the fields of ear, nose & throat, head & neck surgery / reconstructive and plastic surgery / thoracic surgery / ophthalmology / endoscopy

**532217**

**Leufen Medical GmbH**

Gustav-Krone-Straße 7  
14167 Berlin  
Germany

Distribution of medical devices: implants (including medical device variants and custom made medical devices), single-use medical devices, instruments and accessories in the fields of thoracic surgery / pulmonology / gastroenterology / endoscopy / anaesthesia