By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Henke-Sass, Wolf GmbH
Keltenstraße 1
78532 Tuttlingen
Germany

Facility ID Number: F000208

Holds Certificate No: **MDSAP 670283**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021
Canada: Medical Devices Regulations - Part 1 - SOR 98/282
Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act
USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design, development, manufacture, service and distribution of active resectoscopic electrodes and non-active medical endoscopes and accessories, as well as reusable medical injection and application systems for the areas of electrosurgical applications, ENT, neurology, obstetrics & gynaecology, orthopaedics, urology and general surgery.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2017-12-20 Effective Date: 2026-08-01 Expiry Date: 2029-07-31

MDSAP Medical Device Single Audit Program
BSI Group America Inc. is an MDSAP recognised auditing organization

...making excellence a habit.™