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**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2017-12-20 Effective Date: 2021-04-21 Expiry Date: 2023-07-31

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP authorized auditing organization

...making excellence a habit.™

Certificate No: **MDSAP 670283**

Registered Scope:

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.

Design, development, manufacture and distribution of sterile single-use syringes and needles.

Original Registration Date: 2017-12-20 Effective Date: 2021-04-21 Expiry Date: 2023-07-31