

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

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2017-12-20

Effective Date: 2023-08-01

Expiry Date: 2026-07-31



BSI Group America Inc. is an MDSAP recognised auditing organization

Page: 1 of 2

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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.



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Page: 2 of 2

This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](#). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.