Certificate of Registration

QUALITY MANAGEMENT SYSTEM – ISO 13485:2016

This is to certify that:

Henke-Sass, Wolf GmbH
Keltenstraße 1
78532 Tuttlingen
Germany

DUNS Number: 31-732-6411

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 [if design controls are part of the certification]; 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

Design and development, manufacture and distribution, repair and service of medical endoscopes and accessories as well as reusable injection and application systems.

Design and development, manufacture and distribution of single-use syringes, single-use needles and applications systems for blood-saving and -treatment.

For and on behalf of BSI:

Carlos Pitanga, Chief Operating Officer Assurance - Americas

Original Registration Date: 2017-12-20 Effective Date: 2018-09-05 Expiry date: 2020-07-31

...making excellence a habit.™

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