

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003 & EN ISO 13485:2012

This is to certify that:

Henke-Sass, Wolf GmbH

Keltenstraße 1
78532 Tuttlingen
Germany

Holds Certificate Number:

MD 573746

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 & EN ISO 13485:2012 for the following scope:

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 blood treatment.

Design und Entwicklung, Produktion und Vertrieb, Reparatur und Service von medizinischen Endoskopen und Zubehör sowie wiederverwendbaren Injektionssystemen und Applikationssystemen.
Design und Entwicklung, Produktion und Vertrieb von Einmalspritzen, Einmalkanülen und Applikationssysteme zur Blutaufbewahrung und Blutbehandlung.

For and on behalf of BSI:



Frank Lee, EMEA Compliance & Risk Director

Original Registration Date: 17/06/2016

Latest Revision Date: 17/06/2016

Effective Date: 17/06/2016

Expiry Date: 31/07/2017

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Certificate No: MD 573746

Location

Registered Activities

Henke-Sass, Wolf GmbH
Keltenstraße 1
78532 Tuttlingen
Germany

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 blood treatment.

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Henke-Sass, Wolf Sp z o o Polska
Ul Lesna 13
64-300 Nowy Tomysl
Poland

Manufacture of medical endoscopes and accessories, and reusable medical injection and application systems.

Herstellung von medizinischen Endoskopen und Zubehör sowie wiederverwendbaren medizinischen Injektionssystemen und Applikationssystemen.

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