

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

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 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, development, manufacture, distribution, repair and service of reusable medical endoscopes and accessories, as well as reusable medical injection and application systems. Design, development, distribution and control of manufacture of sterile single-use syringes, single-use needles and applications systems for blood saving and blood treatment. Design, Entwicklung, Produktion, Vertrieb, Reparatur und Service von wiederverwendbaren medizinischen Endoskopen und Zubehör, sowie wiederverwendbaren medizinischen Injektionssystemen und Applikationssystemen. Design, Entwicklung, Vertrieb und Überwachung der Herstellung von sterilen Einmalspritzen, Einmalkanülen und Applikationssysteme zur Blutaufbewahrung und Blutbehandlung.



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2016-06-17

Effective Date: 2017-08-01

Latest Revision Date: 2018-08-23

Expiry Date: 2020-07-31



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Certificate No: **MD 573746**

Location

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Keltenstraße 1
78532 Tuttlingen
Germany

Registered Activities

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

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

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An electronic certificate can be authenticated [online](#).

Printed copies can be validated at www.bsigroup.com/ClientDirectory

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