

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:

Please see scope page.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2016-06-17

Latest Revision Date: 2021-01-26

Effective Date: 2020-08-01

Expiry Date: 2023-07-31

Page: 1 of 3



003

...making excellence a habit.™

Certificate No: **MD 573746**

Registered Scope:

Design, development, manufacture, repair 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.

Design, Entwicklung, Herstellung, Reparatur und Vertrieb von aktiven Resektoskopieelektroden und nicht-aktiven medizinischen Endoskopen und Zubehör, sowie wiederverwendbaren medizinischen Injektionssystemen und Applikationssystemen.

Design, Entwicklung, Herstellung und Vertrieb von sterilen Einmalspritzen und Einmalkanülen.



Original Registration Date: 2016-06-17

Latest Revision Date: 2021-01-26

Effective Date: 2020-08-01

Expiry Date: 2023-07-31

Page: 2 of 3

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

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

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

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

Certificate No: **MD 573746**

Location

Henke-Sass, Wolf GmbH
Keltenstraße 1
78532 Tuttlingen
Germany

Registered Activities

Design, development, manufacture, repair 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.

Design, Entwicklung, Herstellung, Reparatur und Vertrieb von aktiven Resektoskopieelektroden und nicht-aktiven medizinischen Endoskopen und Zubehör, sowie wiederverwendbaren medizinischen Injektionssystemen und Applikationssystemen.

Design, Entwicklung, Herstellung und Vertrieb von sterilen Einmalspritzen und Einmalkanülen.

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

Manufacture and repair of non-active medical endoscopes and accessories, as well as reusable medical injection and application systems.

Herstellung und Reparatur von nicht-aktiven medizinischen Endoskopen und Zubehör, sowie wiederverwendbaren medizinischen Injektionssystemen und Applikationssystemen.

Original Registration Date: 2016-06-17

Latest Revision Date: 2021-01-26

Effective Date: 2020-08-01

Expiry Date: 2023-07-31

Page: 3 of 3

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

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

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

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.