

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. CE 573751
Issued To: **Henke-Sass, Wolf GmbH**
Keltenstraße 1
78532 Tuttlingen
Germany

In respect of:

Design and manufacture of active resectoscopic electrodes and non-active medical endoscopes and accessories.

Entwicklung und Herstellung von aktiven Resektoskopieelektroden und nicht aktiven medizinischen Endoskopen und Zubehör.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2016-06-27**

Date: **2020-05-08**

Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

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

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Supplementary Information to CE 573751

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NBOG Code(s)	Device Name	Intended Purpose per IFU
Class IIb		
MD 1104	Resectoscopic electrodes (sterile)	To deliver high-frequency energy for the ablation, incision, coagulation, cauterization of minor bleedings, resection of tissue, vaporization and enucleation
MD 1104	Resectoscopic electrodes (non-sterile)	To deliver high-frequency energy for the ablation, incision, coagulation, cauterization of minor bleedings, resection of tissue, vaporization and enucleation
Class IIa		
MD 0106	Rigid endoscopes and accessories (non-sterile)	---

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