EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

Spiggle & Theis Medizintechnik GmbH

Burghof 14
51491 Overath
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Medical devices as listed in the annex for use in the field of ENT and head & neck surgery.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	056411 MR2
Certificate unique ID	170750476
Effective date	2019-09-03
Expiry date	2024-04-08
Frankfurt am Main	2019-09-03

DQS Medizinprodukte GmbH

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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

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Annex to certificate
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Device family	Devices	Class
Ventilation Tubes	Ventilation Tubes made of Titanium Ventilation Tubes made of Silicone Ventilation Tubes made of PTFE	IIb
Middle Ear Implants	Partial Middle Ear Implants Total Middle Ear Implants Stapes Prostheses	IIb
Lid Implants	Lid Implants made of Platinum/Iridium	IIb
Catheters for use in the field of ENT	Probing and Flushing Catheters (TubaClean®)	IIa
Instruments	Micro Drill- and Shaver-Systems and Accessories Handpieces for Shaver-Systems Rotary Instruments Oscillating Instruments Irrigation-Sets Suction Handles and Adaptors (reusable) Suction and Irrigation Instruments (reusable) Flexible and Rigid Endoscope Systems and Accessories Single-Use Insertion Instruments (TubaInsert®) Single Use Suction Handle ENT Single Use Suction tube (otology, rhinology, laryngology	IIa
Instruments	HF-Instruments	IIb
Rhinological Products	Septal Buttons	IIa