



EC-CERTIFICATE

(Production quality assurance)



This is to certify that the company

Spiggle & Theis Medizintechnik GmbH

Burghof 14
51491 Overath
Germany

has implemented and maintains a quality assurance system which applies to the manufacture and final controls of the products.

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

Annex V 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 V, Section 4. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the 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 MR5

Certificate unique ID 170691079

Effective date 2019-04-09

Expiry date 2024-04-08

Frankfurt am Main 2019-04-09

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

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



Annex to certificate

Certificate registration No.: 056411 MR5

Certificate unique ID: 170691079

Effective date: 2019-04-09

Spiggle & Theis Medizintechnik GmbH

Burghof 14
51491 Overath
Germany

Device family	Device	Class
Instruments	Shortening Scales for Middle Ear Implants	Im
Instruments	Inflation Devices and Accessories Expanding Instrument Wipes made of Polyvinylalcohol (PVA)	Is
Catheters for use in the field of ENT	Choanal Balloon Catheters Epistaxis Balloon Catheters Balloon Catheters for the Tuba Eustachii (TubaVent®)	Is
Sterile Covers	Sterile Drapes for Microscopes and Technical Medical Devices	Is
Rhinological Products	Septum Splints, with or without Respiratory Channel, made of Silicone Septum Splints made of FEP	Is
Tampons	Expanding Products suitable for the Absorption of Body Fluids and Secretions in deep Cavity Wounds made of Polyvinylalcohol (PVA)	Is