



# EU Quality Management Certificate



This is to certify that the company

## Spiggle & Theis Medizintechnik GmbH

Burghof 14  
51491 Overath  
Germany

SRN: DE-MF-000006647

has established, implemented and maintains a Quality Management System in accordance with

### **Annex IX, Chapter I and III of the Regulation (EU) 2017/745 Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation**

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3. Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

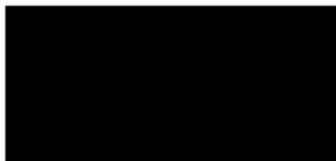
For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	056411 MDR2017Q
Certificate ID	1000202177
Effective date	2024-11-07
Expiry date	2029-10-08
Frankfurt am Main,	2024-11-07



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
BS-MDR-094

## DQS Medizinprodukte GmbH



Heinrich von Mettenheim  
Managing Director



Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main  
**DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745  
of the Council concerning medical devices with the Identification Number 0297.**  
The validity of the certification can only be verified by the QR-code.



**Annex to EU Quality Management Certificate**  
**SRN of Manufacturer: DE-MF-000006647**  
**Certificate ID: 1000202177**

**Device categories and variants covered by this certificate:**

Device category: **MDN 1104 - Non-active soft tissue and other implants**  
Product name: Lid Implants  
Risk classification: Iib  
Basic-UDI-DI: 425038189A0101QY  
Intended purpose: Restoration of dynamic lid closure in paralytic lagophthalmos due to facial nerve paresis.

Device category: **MDN 1203 - Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools**  
Product name: Balloon Catheters for the Tuba Eustachii (TubaVent®, TubaVent® wide)  
Risk classification: Is  
Basic-UDI-DI: 425038188C0101R9  
Intended purpose: Product for dilatation of the Eustachian tube in cases of obstructive tube dysfunction for the specialities of ENT or head and neck surgery.

Device category: **MDN 1203 - Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools**  
Product name: Balloon Catheters for the Tuba Eustachii (TubaVent® short, TubaVent® short wide)  
Risk classification: Is  
Basic-UDI-DI: 425038188C0201RE  
Intended purpose: Product for dilatation of the Eustachian tube in cases of obstructive tube dysfunction for the specialities of ENT or head and neck surgery.

**Examinations and tests performed:**

056411\_A211080MED\_01 dated 2023-08-14  
056411\_A211080MED\_Lid Implants dated 2024-09-17  
056411\_A215419MED TubaVent® Family dated 2024-10-12

**Further conditions for or limitations to the validity of the certificate:**

In case of products that are placed on the market in sterile condition, the involvement of the Notified Body in the conformity assessment procedure is limited to the aspects of manufacture concerned with securing and maintaining sterile condition.

**Reference to previous certificates:**

Revision	Date of Issue	Certificate-ID	Description of change
01	2024-10-09	1000120361	Addition of product TubaVent® Family