



# EU Technical Documentation Assessment Certificate



This is to certify that the company

## Boston Medical Products, Inc.

70 Chestnut Street  
Shrewsbury, MA 01545  
United States of America

SRN: US-MF-000017994

has established and maintains the required Technical Documentation in accordance with

### Annex IX, Chapter II 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 Technical Documentation has been verified and confirmed in Conformity Assessment Procedures according to Article 52. The Technical Documentation is subject to regular surveillance. Limitations to this certificate are listed in the Annex.

Devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing devices listed in the Annex on the market, an additional certificate according to Annex IX, Chapter I and III is required.

Certificate registration no.	488278 MDR2017P
Certificate ID	1000235737
Effective date	2025-04-30
Expiry date	2030-04-29
Frankfurt am Main,	2025-04-30



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlf.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 Technical Documentation Assessment Certificate**  
**SRN of Manufacturer: US-MF-000017994**  
**Certificate ID: 1000235737**

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

Device category: **MDN 1104 - Non-active soft tissue and other implants**  
Product name: LACS  
Models: n/a  
Risk classification: I Ib  
Basic-UDI-DI: 4063107LAK8P  
Intended purpose: Prevention and treatment of laryngeal glottic synechia (anterior glottic stenosis)

**Examinations and tests performed:**

488278\_A211278MED\_03 Laryngeal Anterior Commissure Stent (LACS) LAK dated 2025-03-18

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

n/a

**Reference to previous certificates:**

<b>Revision</b>	<b>Date of Issue</b>	<b>Certificate-ID</b>	<b>Description of change</b>
n/a	n/a	n/a	n/a