EU Quality Management 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, 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.	488278 MDR2017Q
Certificate ID	1000232856
Effective date	2025-04-30
Expiry date	2028-12-27
Frankfurt am Main,	2025-04-30

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

Annex to EU Quality Management Certificate
SRN of Manufacturer: US-MF-000017994
Certificate ID: 1000232856

Authorised Representative of the company:

bess medizintechnik GmbH

Gustav-Krone-Str. 7
14167 Berlin
Germany

SRN: DE-AR-000006514

Device categories and variants covered by this certificate:

Device category:	**MDN 1201- Non-active non-implantable devices for anaesthesia, emergency and intensive care**
Product name:	Montgomery® Long-Term Cannula
Risk classification:	IIb
Basic-UDI-DI:	4063107TCSAM
Intended purpose:	To provide a secondary airway in place of a standard tracheostomy tube or comparable products in order to establish a long-term tracheostoma

Device category:	**MDN 1201- Non-active non-implantable devices for anaesthesia, emergency and intensive care**
Product name:	Moore Tracheostomy Tube
Risk classification:	IIb
Basic-UDI-DI:	4063107MTTB7
Intended purpose:	to maintain an adequate airway while providing support in the stenotic cervical or thoracic trachea

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

Examinations and tests performed:
488278_A211278MED_01 Audit report dated 2023-07-20
488278_A211278MED_02 Montgomery Cannula system dated 2023-11-19
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

Annex to EU Quality Management Certificate
SRN of Manufacturer: US-MF-000017994
Certificate ID: 1000232856

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2023-12-28	170782384	Change to the new certificate template
02	2024-03-22	1000167815	Addition of Product “LACS”