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.

For placing of devices of class IIa, IIb or III 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	170782384
Effective date	2023-12-28
Expiry date	2028-12-27
Frankfurt am Main,	2023-12-28

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

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Michael Bothe
Head of Certification Body
(active medical devices)

Szymon Kurdyn
Head of Certification Body
(non-active medical devices)

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 this certificate can only be verified by the QR-code.

420.90 Version 5.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: US-MF-000017994
Certificate ID: 170782384

Authorised Representative of the company:

bess medizintechnik GmbH

Gustav-Krone-Str. 7
14167 Berlin
Germany

SRN: DE-AR-000006514

Device categories covered by this certificate:

Device category:	**R010503 - TRACHEOSTOMY INNER CANNULAS**
Risk classification:	IIb
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:	**R010503 - TRACHEOSTOMY INNER CANNULAS**
Risk classification:	IIb
Intended purpose:	to maintain an adequate airway while providing support in the stenotic cervical or thoracic trachea

Examinations and tests performed:
488278_A211278MED_01 dated 2023-07-20

Further conditions for or limitations to the validity of the certificate:
The manufacturer's quality management system is subject to periodic surveillance in accordance with Annex IX, Chapter 1, Section 3.

Reference to previous certificates:

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