



EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

Boston Medical Products, Inc.

70 Chestnut Street
Shrewsbury, MA 01545
United States of America

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

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

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Head & Neck Surgery Products, Interdisciplinary Products according to annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this 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.	488278 MR2
Certificate unique ID	170773614
Effective date	2021-04-06
Expiry date	2024-05-26
Frankfurt am Main	2021-04-06

DQS Medizinprodukte GmbH

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Dr. Thomas Feldmann
Head of Certification Body

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
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Device family	Device	Class
Head & Neck Surgery Products	Tracheostomy Tubes	IIb
	Respiratory Stents	IIb
	Thyroplasty Implants	IIb
	Esophageal Stents and Tubes	IIb
	Laryngeal Stents and Keels	IIb
	Cannula Speaking Valves	IIa
	Tracheostomy Speaking Valves	IIa
	Cannulas	IIa
	Thyroplasty Instruments	IIa
	Rhinology Catheters	IIa
	Nasal Splints	IIa
Tracheostomy Instruments	Is	
Interdisciplinary Products	Silicone Sheetings unrestricted	IIb
	Silicone Sheetings and Strips restricted	IIa