

# CERTIFICATE

Management system as per

**ISO 13485:2016**

The Certification Body TUV USA, Inc. hereby confirms as a result of the audit, assessment and certification decision according to ISO/IEC 17021-1:2015, that the organization

**BMC Medical Manufacturing S.A. de C.V.**

**Ave. TLC 5010-2**

**Apodaca, N.L. 66626**

**Mexico**

**with the locations according to the annex**

operates a management system in accordance with the requirements of ISO 13485:2016 for Medical Devices-Quality Management Systems-Requirements for Regulatory Purposes and will be assessed for conformity within the 3 year term of validity of the certificate.

Scope

**Design and Development, Manufacturing and Sale of Sterile Percutaneous Transluminal Angioplasty Balloon Catheters and Sterile Balloon Insufflators**

**Contract Manufacture of Sterile Thoracic Stents Grafts and Sterile Embolization Coils Systems**

Certificate Registration No. 23-1605-Q

Audit Report No. 23-4046 CA

Valid from 2023-12-02

Valid until 2026-12-01

Initial certification 2023-12-02



Certification Body  
at TUV USA, Inc.

Salem, NH 2023-12-02, ed. 1

# ANNEX

to Certificate Registration No. 23-1605-Q  
ISO 13485 : 2016

**BMC Medical Manufacturing S.A. de C.V.**  
Ave. TLC 5010-2  
Apodaca, N.L. 66626  
Mexico

## Location

BMC Medical Manufacturing S.A. de C.V.  
Ave. TLC 5010-2  
Apodaca, N.L. 66626  
Mexico


BMC Medical Manufacturing S.A. de C.V.  
Mina N° 102 Col. Emiliano Zapata  
Monterrey, N.L. 64390  
Mexico

## Scope

Design and Development,  
Assembly, Production,  
Packaging and Labeling,  
Storage, Quality Assurance  
and Inspection, Management  
Activities

ETO Sterilization Process,  
Storage

End of the List



Certification Body  
at TUV USA, Inc.

Salem, NH 2023-12-02, ed. 1

TUV USA, Inc.

215 Main Street, Salem, NH 03079, USA

[www.tuv-nord.com/us](http://www.tuv-nord.com/us)

