



# Certificate of Registration

# QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

## IIMED Medical Mexicana,

**S. de R.L. de C.V.** Ave. Mike Allen 1220, Edificio 5 Parque Industrial Reynosa Sección Norte Reynosa Tamaulipas C.P. 88788 Mexico

Holds Certificate Number:

FM 561496

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Assembly and final packaging of Sterile Passive Markers, Compression Therapy Devices, Pressure Infusers, Sterile and Non- Sterile Urodynamic Catheters, Kits and Accessories, Sterile Wire Electrode Needle Set, Orthopedic/ Orthoses, Anesthesia/ Respiratory Circuits and Accessories, Blood Pressure Cuffs, Lift Medical Devices, Urine Drainage Bags, Pressure Ulcer Prevention Device and AC-powered / non-AC powered Patient Lifting Device, Cuff Tourniquets and Oral Care Products.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2010-06-09 Latest Revision Date: 2024-09-13 Effective Date: 2022-06-09 Expiry Date: 2025-06-08

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...making excellence a habit."

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated <u>online</u>. Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact:

BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | Tel: +31 20 3460 780 BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V. Americas Headquarters: 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA

### Certificate No: FM 561496

#### Location

IIMED Medical Mexicana, S. de R.L. de C.V. Ave. Mike Allen 1220, Edificio 5 Parque Industrial Reynosa Sección Norte Reynosa Tamaulipas C.P. 88788 Mexico

iiMED Medical Mexicana S. de R.L. de C.V Avenida Mike Allen # 1180 Lote 9 Parque Industrial Reynosa Sección Norte. C.P 88788 Reynosa Tamaulipas Mexico

#### **Registered Activities**

Assembly and final packaging of Sterile Passive Markers, Compression Therapy Devices, Pressure Infusers, Sterile and Non- Sterile Urodynamic Catheters, Kits and Accessories, Sterile Wire Electrode Needle Set, Orthopedic/ Orthoses, Anesthesia/ Respiratory Circuits and Accessories, Blood Pressure Cuffs, Lift Medical Devices, Urine Drainage Bags, Pressure Ulcer Prevention Device and AC-powered / non-AC powered Patient Lifting Device, Cuff Tourniquets and Oral Care Products.

Assembly and final packaging of Cuff Tourniquets and Oral Care Products.

## Original Registration Date: 2010-06-09 Latest Revision Date: 2024-09-13

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