

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Martech Medical Products,
S. de R.L. de C.V.
Calle Mercurio N 46
Parque Industrial Mexicali 1
Mexicali
Baja California
C.P. 21210
Mexico

Holds Certificate No:

FM 578605

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

Manufacturing and packaging of sterile and non-sterile medical components and finished medical devices consisting of plastics and silicone, through processes of extrusion, tipping, molding, drilling, printing and assembly. Product applications include, but are not limited to: short and long term surgical procedures in dialysis, hematology, oncology, urology, infusion/transfusion, vascular access, cardiac rhythm management and pain management.

This certificate is traceable to this company's original registration certificate number S 951 06 3997 dated January 26, 2011 and issued by TÜV SÜD America Inc.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2011-09-30

Latest Revision Date: 2018-12-14

Effective Date: 2019-01-06

Expiry Date: 2022-01-05

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