

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Polimeros Formula de Tecate S.A. de C.V.

Calle Guaycura No. 106
Col. El Paraiso
Tecate
Baja California
21485
Mexico

Holds Certificate Number:

FM 716979

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

Contract manufacturer of plastic injected molding of subassemblies and final assembly and packaging of medical devices.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2020-01-31

Latest Revision Date: 2025-11-09

Effective Date: 2026-01-31

Expiry Date: 2029-01-30

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