



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

ProMed Molded Products dba ProMed Pharma, LLC

15600 Medina Rd.

Plymouth Minnesota 55447 USA

Holds Certificate Number:

FM 560649

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

Contract manufacturing of sterile medical devices, drug combination medical devices, and plastic and silicone molded components, including components with a pharmaceutical active ingredient.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

C. ESSEL

Original Registration Date: 2010-05-18 Latest Revision Date: 2025-03-13 Effective Date: 2024-01-01 Expiry Date: 2026-12-31

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Location Registered Activities **ProMed Molded Products** Contract manufacturing of sterile medical devices, drug combination medical devices, and plastic and silicone molded dba ProMed Pharma, LLC components, including components with a pharmaceutical 15600 Medina Rd. active ingredient. Plymouth Minnesota 55447 USA **ProMed Molded Products** Contract manufacture of molded plastic and silicone components for the medical device industry. dba ProMed Pharma, LLC 7 Road 696 Dorado 00646-3306 Puerto Rico

ProMed Molded Products dba ProMed Pharma, LLC 6765 Wedgwood Rd. N Maple Grove Minnesota 55311 USA

Certificate No:

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Contract manufacturing of medical devices, drug combination medical devices, and plastic and silicone molded components, including components with a pharmaceutical active ingredient.

ProMed Molded Products 15255 23rd Avenue North Plymouth Minnesota 55447

USA

Contract manufacture of molded plastic and silicone components for the medical device industry.

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Information and Contact: