

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Medline Industries, LP  
Three Lakes Drive  
Northfield  
Illinois  
60093  
USA

Holds Certificate No:

**FM 702756**

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

Please see scope page.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2009-10-01

Latest Revision Date: 2021-10-08

Effective Date: 2019-12-02

Expiry Date: 2022-12-01



Certificate No: **FM 702756**

## Registered Scope:

Design, manufacturing, and distribution of disposable medical devices and associated equipment. Durable Medical Equipment: Wheelchairs and Patient Aids. Respiratory Products: Regulators, Masks, Nebulizers, Breathing Bags. Furniture Products: Pressure Relief Mattresses, Furniture and Beds. Wound Care Gels and Dressings. Measuring Products: Thermometers, Blood Pressure and Glucose Testing Systems. Electrosurgical and Surgical Instruments and Supplies. Hot/Cold Therapy Products, Restraints, Urological and Suction/Irrigation Products, Sterile and Non-Sterile Procedure Trays and Components for Anesthesia, and Face Masks.

Design, manufacture, service and distribution of Enteral feeding tubes, pumps and sets, Deep Vein Thrombosis Systems including Garments, and Sterilization containers.

Manufacture and distribution of sterile, pre-filled saline flush syringes for IV lines. Sterile and Non-Sterile Procedure Trays and Components for Airways, Angiography, Arthroscopy, Basin, Biopsy, Breast Reduction, Bronchoscopy, Cardiovascular, Cath Lab, Dental, Dressing, Endoscopy, ENT, Extremity, Eye, Gastro/Urol, General Surgery, Gynecology, Hemodialysis, Irrigation, Obstetrics, Laceration, Laparoscopy, Neurology, Ophthalmic, Orthopedic, Trach Care, Thoracic, Urethral Applications. Bone Wax, Sutures, Collagen Medical Patch, Ligation Clips, external ECG Electrodes, Patient Warming Mattress, High Viscosity Tissue Adhesive, Skin Staplers. Personal Hygiene wipes and associated cleaning products, Bag/Liners, Blankets, Bibs, Catheters, Disposable Apparel, Disposable Incontinence Products, Draperies, Drapes, Examination and Surgical Gloves Gauze/Bandages, Needles/Syringes, Reusable Underpads and Briefs, Tapes, Scrubs, Sharps Containers, Sheets, Sponges, Slippers, Table Linen, Towels, Towels/Washcloths, Tubing, Cotton Tipped Applicators, Sterile and Non-Sterile Lubricating Jelly and non-sterile Ultrasound Gel, and Sterile pre filled saline for injection syringes.

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To be read in conjunction with the scope above or the attached appendix.

Certificate No: **FM 702756**

Location	Registered Activities
Medline Industries, LP 10 Glens Falls Technical Park Drive Glens Falls New York 12801 USA	Design and development, manufacture, distribution and regulatory activities of sterile and non-sterile, disposable and reusable, active and non-active medical devices and kits, including: guide wires; torque devices, fluid administration devices; fluid management devices, high pressure lines; pressure monitoring devices and associated accessories for the area of cardiovascular and radiological intervention procedures for the access, diagnosis and treatment of vascular and non-vascular diseases and conditions.
Medline Industries, LP 550 Research Parkway Meriden Connecticut 06450 USA	Manufacture, and distribution of disposable sterile skin preparation products.
Medline Industries, LP 12001 General Milton Drive Laredo Texas 78045 USA	Manufacturing and distribution of sterile and non-sterile procedure trays/kits and associated components/equipment. Sterile and Non-Sterile Procedure Trays/Kits and Components/Equipment for: Anesthesia, Airways, Angiography, Arthroscopy, Basin, Biopsy, Breast, Bronchoscopy, Cardiovascular, Cath Lab, Dental, Dressing, Endoscopy, ENT, Extremity, Eye, Gastro/Urology, General Surgery, Gynecology, Hemodialysis, Irrigation, Obstetrics, Laceration, Laparoscopy, Neurology, Ophthalmic, Orthopedic, Trach Care, Thoracic, Urethral Applications.
Medline Industries, LP Three Lakes Drive Northfield Illinois 60093 USA	Regulatory, Administration, Design activity.
Medline Industries, LP 1170 Northpoint South Waukegan Illinois 60085 USA	Manufacturing and distribution of sterile and non-sterile custom procedure trays / kits and associated equipment.

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Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA  
A Member of the BSI Group of Companies.

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Location	Registered Activities
Productos Medline S.A. de C.V. Blvd. World Trade Center No. 106 Parque Industrial Oradel Nuevo Laredo Tamaulipas C.P. 88285 Mexico	Manufacturing and Distribution of Disposable Custom Procedure Trays/kits, associated equipment and the Injection Molding, Extrusion and Assembly of plastic parts for use in Respiratory and Anesthesia Products.
Caring International Three Lakes Drive Northfield Illinois 60093 USA	Design and distribution of disposable medical devices and associated equipment.  Wound Care Gels & Dressings, Disposable Incontinence Products, Examination and Surgical Gloves, Gauze/Bandages and Tapes.
Medline Industries, LP 9103 Riverside Parkway Lithia Springs Georgia 30122 USA	Manufacturing of adult disposable incontinence products.
Medline Industries, LP 9101 Riverside Parkway Lithia Springs Georgia 30122 USA	Distribution
Medline Industries, LP 700 W North Shore Drive Hartland Wisconsin 53029 USA	Manufacture and Packaging of Sterile Lubricating Jelly. Manufacture of sterile, pre-filled saline flush syringes for IV lines.
Medline Industries, LP 1200 Townline Road One Medline Place Mundelein Illinois 60060 USA	Injection and Blow molding of medical plastic products such as male urinals, sharps containers, suction canisters, bed pans and emesis basins.

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