bsi.

By Royal Charter

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 Number: 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:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2009-10-01
Latest Revision Date: 2025-07-16

Effective Date: 2025-08-19
Expiry Date: 2028-08-18

...making excellence a habit.™

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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 702756

Registered Scope:

Design, manufacturing, and distribution of disposable medical devices and associated equipment. Durable Medical Equipment: Wheelchairs and Patient Aids. Respiratory Products and Accessories for Oxygen and Medicine Delivery, Airway Management, Bronchial Hygiene, and Ventilation: Regulators, Masks, Nebulizers, Breathing Bags, Humidifiers, Incentive Spirometers, Aerosol Heaters, Adaptors, Connectors, Oxygen Supply Tubing, Aerosol Tubing, Nasal Cannulas, Respiratory Circuits (Heated Wire and Non-Heated), Single Unit Dose Vials, Sterile Water Reservoirs and Columns, Temperature Probes. 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 devices (fluid feeding pathways) and components such as machines, tubing, valves, bags, adapters, clamps, connectors, and accessories. Tubes, pumps and sets, Deep Vein Thrombosis Systems including Garments, and Sterilization containers, and vascular items (angiography, cardiovascular, cath lab products).

Manufacture and distribution of sterile, pre-filled saline flush syringes for IV lines. Sterile and Non-Sterile Procedure Trays and Components for Anesthesia, Airways, Angiography, Arthroscopy, Basin, Biopsy, Breast Reduction, Bronchoscopy, Cardiovascular, Cath Lab, Dental, Dressing, Endoscopy, ENT, Extremity, Eye, Gastro/Urology, General Surgery, Gynecology, Hemodialysis, Irrigation, Obstetrics, Laceration, Laparoscopy, Neurology, Opthalmic, Orthopedic (washers, staples, plates and screws), 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 nonsterile Ultrasound Gel, and Sterile pre filled saline for injection syringes.

Reprocessing of single-use surgical instruments.

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Location	Registered Activities
Medline Industries, LP 10 Glens Falls Technical Park Drive Glens Falls New York 12801 USA	Design and development, manufacture, and regulatory activities of sterile and nonsterile, 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 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 Reduction, Bronchoscopy, Cardiovascular, Cath Lab, Dental, Dressing, Endoscopy, ENT, Extremity, Eye, Gastro/Urology, General Surgery, Gynecology, Hemodialysis, Irrigation, Obstetrics, Laceration, Laparoscopy, Neurology, Ophthalmic, Orthopedic (washers, staples, plates, and screws), Trach Care, Thoracic, Urethral Applications. Re-processing Single-use Surgical Instruments.
Medline Industries, LP Calle Circuito Del Desierto 71 Parque Industrial Del Desierto Mexicali Baja California 21383 Mexico	Manufacturing 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 Reduction, Bronchoscopy, Cardiovascular, Cath Lab, Dental, Dressing, Endoscopy, ENT, Extremity, Eye, Gastro/Urology, General Surgery, Gynecology, Hemodialysis, Irrigation, Obstetrics, Laceration, Laparoscopy, Neurology, Ophthalmic, Orthopedic (washers, staples, plates, and screws), 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 disposable medical devices and associated equipment.

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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 of sterile, pre-filled saline flush syringes for IV lines. Manufacturing and packaging of disinfectant wipes for hard non-porous surfaces.
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, bed pans and emesis basins.

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