

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Medline Industries, Inc.
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:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2009-10-01

Latest Revision Date: 2019-11-22

Effective Date: 2019-12-02

Expiry Date: 2022-12-01

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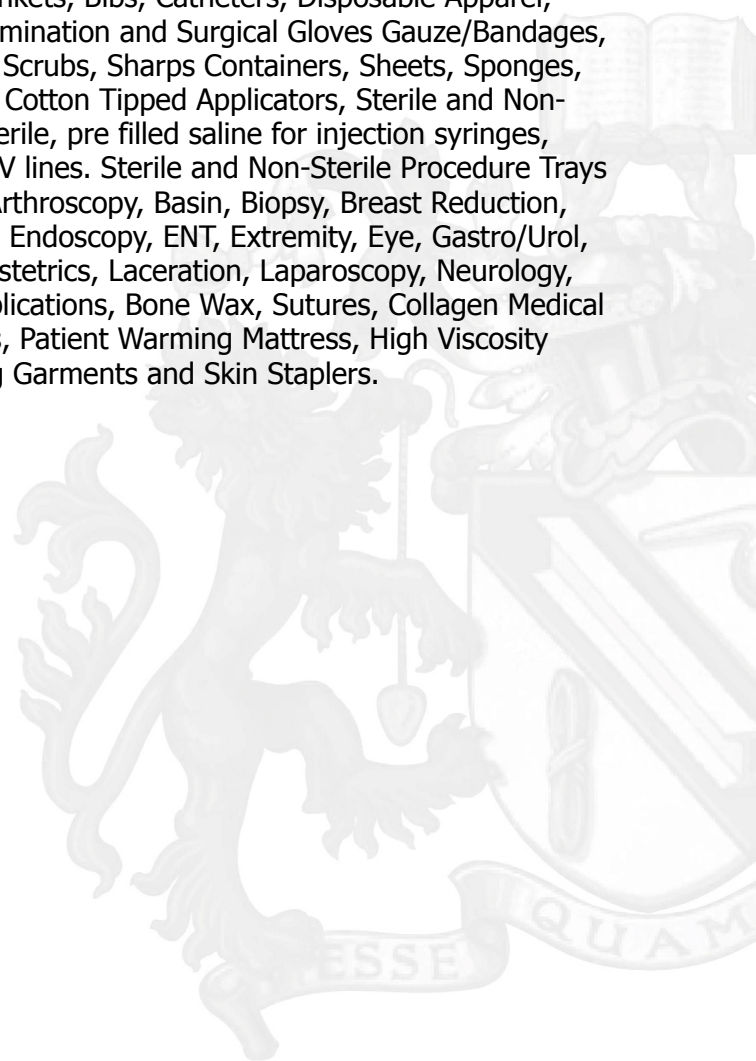


...making excellence a habit.™

Certificate No: **FM 702756**

Registered Scope:

Design, manufacturing, and distribution of disposable medical devices and associated equipment. Durable Medical Equipment: Wheelchairs, Patient Aids Respiratory Products: Regulators, Masks, Nebulizers, Breathing Bags Furniture Products: Pressure Relief Mattresses, Furniture and Beds, Enteral feeding tubes, pumps and sets, Wound Care Gels and Dressings, Measuring Products: Thermometers, Blood Pressure and Glucose Testing Systems Personal Hygiene wipes and associated cleaning products Electrosurgical and Surgical Instruments and Supplies Hot/Cold Therapy Products and Restraints Urological and Suction/Irrigation Products Misc. supplies: 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, Sterile, pre filled saline for injection syringes, Manufacture 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/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, Face Masks, external ECG Electrodes, Patient Warming Mattress, High Viscosity Tissue Adhesive, Deep Vein Thrombosis Systems including Garments and Skin Staplers.



Original Registration Date: 2009-10-01

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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, Inc. Three Lakes Drive Northfield Illinois 60093 USA	Administration.
Medline Industries, Inc. 1170 Northpoint South Waukegan Illinois 60085 USA	Manufacturing and distribution of sterile and non-sterile customer procedure trays / kits and associated equipment.
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, Inc. 9103 Riverside Parkway Lithia Springs Georgia 30122 USA	Manufacturing and distribution of adult disposable incontinence products.
Medline Industries, Inc. 700 W North Shore Drive Hartland Wisconsin 53029 USA	Manufacture and Packaging of Sterile and Non-sterile Lubricating Jelly and non-sterile Ultrasound Gel. Manufacture of sterile, pre-filled saline flush syringes for IV lines.

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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.

Certificate No: **FM 702756**

Location

Medline-Temecula
41980 Winchester Road
Temecula
California
92590
USA

Registered Activities

The assembly and distribution of sterile and non-sterile custom packaged hospital supply trays and integrated delivery systems.

Medline Industries, Inc.
1200 Townline Road
One Medline Place
Mundelein
Illinois
60060
USA

Manufacture and Distribution of Disposable Customer Procedure Trays/Kits and Injection and Blow molding of medical plastic products such as male urinals, sharps containers, suctions canisters, bed pans and emesis basins.



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