

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Medline Industries, Inc.
Three Lakes Drive
Northfield
Illinois
60093
USA

Facility ID Number: F001901

Holds Certificate No:

MDSAP 690356

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2019-08-19

Effective Date: 2020-12-08

Expiry Date: 2022-08-18



BSI Group America Inc. is an MDSAP authorized auditing organization

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Certificate No: **MDSAP 690356**

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, Face Masks.

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

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, Sterile, pre filled saline for injection syringes.

Original Registration Date: 2019-08-19 Effective Date: 2020-12-08

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

Certificate No: **MDSAP 690356**

Location	Registered Activities
Medline Industries, Inc. Three Lakes Drive Northfield Illinois 60093 USA Facility ID Number: F001901	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, Face Masks. Design, manufacture, service and distribution of Enteral feeding tubes, pumps and sets. Deep Vein Thrombosis Systems including Garments. 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, Sterile, pre filled saline for injection syringes.
Medline Industries, Inc. 700 W North Shore Drive Hartland Wisconsin 53029 USA Facility ID Number: F001902	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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Certificate No: **MDSAP 690356**

Location	Registered Activities
Medline Industries, Inc. 1200 Townline Road One Medline Place Mundelein Illinois 60060 USA Facility ID Number: F000290	Injection and Blow molding of medical plastic products such as male urinals, sharps containers, suctions canisters, bed pans and emesis basins.
Medline Industries Inc 10 Glens Falls Technical Park Drive Glens Falls New York 12801 USA Facility ID Number: F004799	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.



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