

COUNTRY OF DESTINATION: CHILE

**APOSTILLE** (Convention de La Haye du 5 Octobre 1961)

1. Country:

United States of America

This public document

2. has been signed by

MARY K LEONARD

3. acting in the capacity of NOTARY PUBLIC, LAKE COUNTY

4. bears the seal/stamp of STATE OF ILLINOIS

Certified

5. at

CHICAGO, ILLINOIS

6. the JULY 31, 2020

7. by

Secretary of State, State of Illinois

8. No.

C20JW136567

9. Seal/Stamp:

10. Signature:



SECRETARY OF STATE STATE OF ILLINOIS

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This Apostille only certifies the signature and the seal or stamp it bears. It does not certify content of the document for which it was issued.

THIS APOSTILLE IS NOT VALID WITHIN THE UNITED STATES OF AMERICA



Medline Industries, Inc.

Three Lakes Drive Northfield, IL 60093 1.847.949.5500 1.800.MEDLINE (633.5463)

medline.com

July 29, 2020

MUNNICH CHILE

Re: Authentication of the ISO 13485: 2016 Certification (Certificate no: FM 702756) of Medline Industries, Inc.

I attest the attached ISO 13485: 2016 certification (Certificate no: FM 702756) with expiration date of December 1<sup>st</sup> of 2022 from Medline Industries, Inc. is a true and accurate reproduction of the original certification.

Best Regards,

Alexander Delgado

International Regulatory Specialist - Latin America

Alexander Velynder

Medline Industries, Inc.

Three Lakes Drive

Northfield, IL 60093 USA

(847) 643-4226

State of | | | | | | | | | | |

County of COOK

Signed or attested before me on 129 20 (date) by ALEXANDER DELGADO (name/s of

person/s).

Many Koluma (Signature of Notary Public)

OFFICIAL SEAL
MARY K LEONARD
NOTARY PUBLIC, STATE OF ILLINOIS
LAKE COUNTY
MY COMMISSION EXPIRES 11/09/2021

ADVANCING THE HEALTH OF HEALTH ARE:





## 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

bsi.



Effective Date: 2019-12-02 Expiry Date: 2022-12-01

Page: 1 of 4

...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, Opthalmic, 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 Latest Revision Date: 2019-11-22 Effective Date: 2019-12-02 Expiry Date: 2022-12-01

Page: 2 of 4

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.

Original Registration Date: 2009-10-01 Latest Revision Date: 2019-11-22

Effective Date: 2019-12-02 Expiry Date: 2022-12-01

Page: 3 of 4

Certificate No:

FM 702756

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**USA** 

**USA** 

## Registered Activities

Medline-Temecula 41980 Winchester Road Temecula California 92590 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 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.

Original Registration Date: 2009-10-01 Latest Revision Date: 2019-11-22 Effective Date: 2019-12-02 Expiry Date: 2022-12-01

Page: 4 of 4

This certificate remains the property of BSI and shall be returned immediately upon request.

An electronic certificate can be authenticated <u>online</u>. Printed copies can be validated at www.bsigroup.com/ClientDirectory

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