

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

O & M Halyard, Inc.
9120 Lockwood Blvd
Mechanicsville
Virginia
23116
USA

Holds Certificate No:

FM 697013

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

The design and development, manufacture and distribution of surgical gowns, protective garments, face masks, surgical drapes, orthopedic soft goods, patient care products, cold therapy products, C-Section packs, OB Packs, orthopedic packs, sterile and non-sterile examination gloves, Temperature management systems for the areas of general surgery and general medical use and sterilization wrap and non-woven materials for medical devices.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2014-12-09

Latest Revision Date: 2019-02-27

Effective Date: 2019-01-01

Expiry Date: 2020-01-08

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...making excellence a habit.™

Certificate No: **FM 697013**

| Location | Registered Activities |
|--|---|
| O & M Halyard, Inc. 9120 Lockwood Blvd Mechanicsville Virginia 23116 USA | Headquarter management activities. |
| O & M Halyard, Inc. 5405 Windward Parkway Alpharetta Georgia 30004 USA | The design and development of surgical gowns, protective garments, face masks, surgical drapes, orthopedic soft goods, patient care products, cold therapy products, C-Section packs, OB Packs, orthopedic packs, sterile and non-sterile examination gloves, Temperature management systems for the areas of general surgery and general medical use and sterilization wrap and non-woven materials for medical devices. |
| Halyard North Carolina, LLC 389 Clyde Fitzgerald Rd. Linwood North Carolina 27299 USA | The manufacture of nonwoven materials for medical devices, Sterilization wrap, and infection control products including disposable gowns and linens. |
| La Ada de Acuna 14 Finegan Road Del Rio Texas 78840 USA | Receiving and Incoming Inspection, Warehouse and Distribution. |
| O&M Halyard Honduras S.A. de C.V. Carretera Tegucigalpa Villanueva Cortes Honduras | The manufacture and distribution of disposable sterile and non-sterile surgical gowns. |
| La Ada de Acuna Avenida Hidalgo #16 Parque Industrial San Carlos Nogales Sonora 84092 Mexico | Receiving and incoming inspection. Manufacturer/Conversion of nonwoven materials. |

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

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 |
|--|--|
| La Ada de Acuna Kim. 4.5 Carreterra Presa La Amistad Ciudad De Acuna Coahuila 26220 Mexico | The manufacture of non-sterile face masks (surgical isolation, industrial and respirator), non-surgical gowns, cold therapy products, and sterilization wrap. |
| La Ada de Acuna S.De. R.L. De C.V AV. Hidalgo #6 Esq., Blvd., Luis Donaldo Colosio, Col. Educativa Nogales Sonora 84093 Mexico | The manufacture of disposable products including sterile and non sterile surgical packs, gowns and components. The manufacture of temperature management systems for areas of general surgery. |
| Safeskin Medical & Scientific (Thailand) Ltd. 200 Moo 8, Kanchanavanich Road, Tambol Prik, Amphur Sadao, Songkhla 90120 Thailand | The design and development, production and distribution of industrial gloves, sterile and non-sterile examination gloves. |



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