

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

This is to certify that:

Halyard Health, Inc.
5405 Windward Parkway
Alpharetta
Georgia
30004-3894
USA

Holds Certificate No:

FM 620884

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 for the following scope:

Please see scope page.

For and on behalf of BSI:



Carlos Pitanga, SVP, System Certification and Compliance

Original Registration Date: 12/09/2014

Effective Date: 01/09/2017

Expiry Date: 02/28/2019



CMDCAS
Recognized
Registrar



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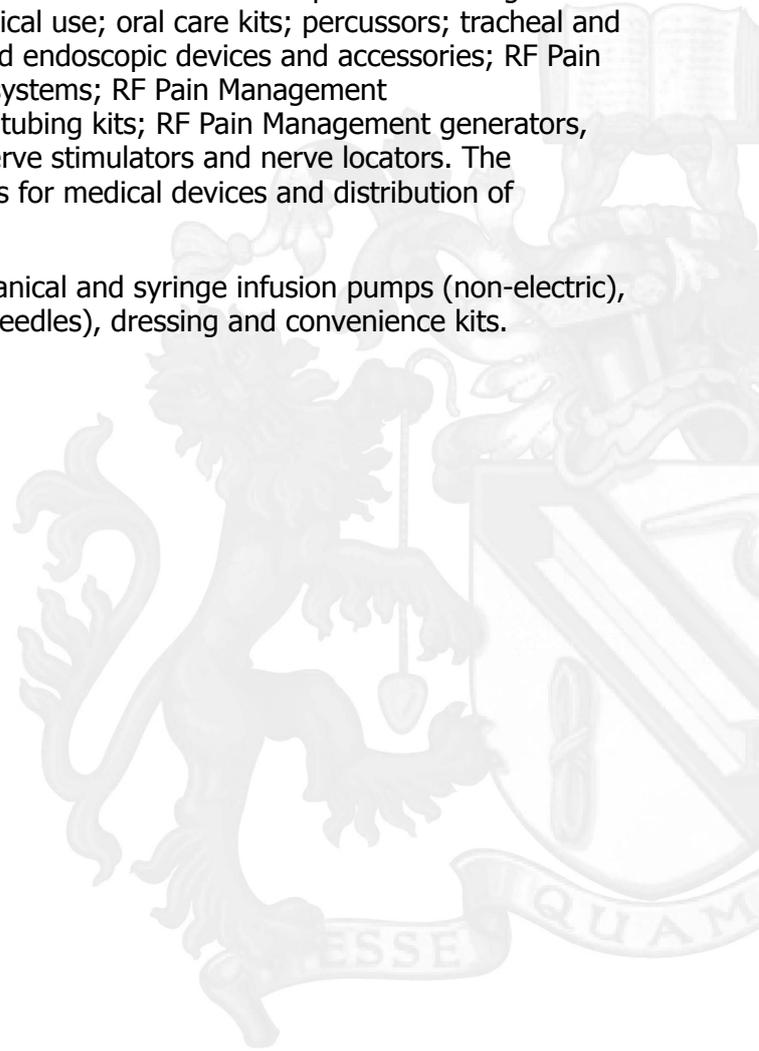
...making excellence a habit.™

Certificate No: **FM 620884**

Registered Scope:

The design, manufacture, and distribution of surgical gowns, protective garments, face masks, surgical drapes, surgical packs, orthopedic soft goods, patient care products, cold therapy products, C-Section packs, OB Packs, orthopedic packs, sterile enteral feeding and access devices; non sterile lavage systems and sample collection kits, non sterile safety drains for respiratory care; sterile pain management kits; sterile respiratory care packs; sterile anesthesia conduction needles and kits; saline vials, in vitro diagnostic test kits for gastroenterology; sterile gastro intestinal tubes and kits; sterile paracentesis trays and kits; and endotracheal tubes, and manufacture of catheters to add silver. Temperature management systems for the areas of general surgery and general medical use; oral care kits; percussors; tracheal and oral suction systems and accessories, bal cath systems and endoscopic devices and accessories; RF Pain Management systems and accessories used within those systems; RF Pain Management cannulas/introducers, cooled and non-cooled probes, and tubing kits; RF Pain Management generators, pumps and pressure monitoring devices and peripheral nerve stimulators and nerve locators. The manufacture of sterilization wrap and non woven materials for medical devices and distribution of microbial sealant.

Design and development of disposable elastomeric, mechanical and syringe infusion pumps (non-electric), pump fillers, administration sets, catheters, introducers (needles), dressing and convenience kits.



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Location	Registered Activities
La Ada de Acuna 14 Finegan Road Del Rio Texas 78840 USA	Warehouse.
Avent S. de R.L. de C.V. Privada Baja California Edificio B2 Fraccionamiento, Rubio Tijuana Baja California 22116 Mexico	Warehouse, manufacture and labeling. Manufacture of catheters, kits, silicone pumps and needles.
I-Flow, LLC 15440 Laguna Canyon Suite 130 Irvine California 92618 USA	R & D Lab and Complaint Lab.
Avent S. de R.L. de C.V. Avenida Hidalgo #1 y Luis Donaldo Colosio Parque Industrial San Carlos Nogales Sonora 84092 Mexico	Receiving Inspection, purchasing and distribution.
Avent S. de R.L. de C.V. Avenida Hidalgo #16 Parque Industrial San Carlos Nogales Sonora 84092 Mexico	Receiving and receiving inspection.

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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.

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Location	Registered Activities
Halyard Health, Inc. 5405 Windward Parkway Alpharetta Georgia 30004-3894 USA	<p>The design, manufacture, and distribution of surgical gowns, protective garments, face masks, surgical drapes, surgical packs, orthopedic soft goods, patient care products, cold therapy products, C-Section packs, OB Packs, orthopedic packs, sterile enteral feeding and access devices; non sterile lavage systems and sample collection kits, non sterile safety drains for respiratory care; sterile pain management kits; sterile respiratory care packs; sterile anesthesia conduction needles and kits; saline vials, in vitro diagnostic test kits for gastroenterology; sterile gastro intestinal tubes and kits; sterile paracentesis trays and kits; and endotracheal tubes, and manufacture of catheters to add silver. Temperature management systems for the areas of general surgery and general medical use; oral care kits; percussors; tracheal and oral suction systems and accessories, bal cath systems and endoscopic devices and accessories; RF Pain Management systems and accessories used within those systems; RF Pain Management cannulas/introducers, cooled and non-cooled probes, and tubing kits; RF Pain Management generators, pumps and pressure monitoring devices and peripheral nerve stimulators and nerve locators. The manufacture of sterilization wrap and non woven materials for medical devices and distribution of microbial sealant.</p> <p>Design and development of disposable elastomeric, mechanical and syringe infusion pumps (non-electric), pump fillers, administration sets, catheters, introducers (needles), dressing and convenience kits.</p>
Avent Inc. 6620 S. Memorial Place, Suite 100 Tucson Arizona 85756 USA	<p>The manufacture and distribution of: Pain Management (including Sterile Anesthesia products) kits and associated components; in vitro diagnostic test kits for gastroenterology, Sterile Gastro Intestinal tubes and Kits; Sterile Paracentesis Trays and Kits; oral care kits; accessories for peripheral nerve stimulators and nerve locators; and manufacture of catheters to add silver.</p>
Avent S. de R.L. de C.V. Circuito Industrial No 40 Colonia Obrera Nogales CP 84048 Mexico	<p>The manufacture and distribution of: Sterile Enteral Feeding and Access Devices; Sample Collection Kits; Non Sterile Safety Drains for Respiratory Care, endotracheal tubes, and sterile Pain Management Kits.</p>
Avent de Honduras, S.A. de C.V. Carretera Tegucigalpa Villanueva Cortes Honduras	<p>The manufacture and distribution of disposable sterile and non-sterile surgical gowns.</p>

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Avent S. de R.L. de C.V. AV. Hidalgo #6 Esq., Blvd., Luis Donald Colosio, Col. Educativa Nogales CP 84093 Mexico	The manufacture of disposable products including sterile and non-sterile surgical packs, gowns and components.
Avent S. de R.L. de C.V. Avenida El Castillo #17-B Nogales CP 84094 Mexico	The manufacture and distribution of sterile Respiratory Care Packs (including saline vials) and molding of enteral feeding and respiratory components.
La Ada de Acuna Km. 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.
Avent S. de R.L. de C.V. Carretera Internacional Salida Norte 1053 Magdalena Sonora CP 84160 Mexico	The manufacture and distribution of temperature management systems for the areas of general surgery and general medical use; oral care kits; percussors; tracheal and oral suction systems and accessories, bal-cath systems and endoscopic devices and accessories; RF Pain Management systems and accessories used within those systems; RF Pain Management cannulas/introducers, cooled and non-cooled probes, and tubing kits.
Halyard Health North Carolina, Inc. 389 Clyde Fitzgerald Road Linwood North Carolina 27299 USA	The manufacture of nonwoven materials for medical devices, Sterilization wrap, and infection control products including disposable gowns and linens.
Avent S. de R.L. de C.V. Ave Noruega Edificio D-1B Fraccionamiento, Rubio Tijuana B.C. 22116 Mexico	Manufacture of Disposable and Reusable Elastomeric, Mechanical and Syringe Infusion Pumps (Non-Electric), Pump Fillers, Administration Sets, Catheters, Introducers (Needles), Dressing, Convenience Kits.

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Location

Halyard - Irvine
43 Discovery, Suite 100
Irvine
California
92618
USA

Registered Activities

Design and Development and Complaint Handling of Disposable Elastomeric, Mechanical and Syringe, Infusion Pumps (Non-Electric), Pump Fillers, Administration Sets, Catheters, Introducers (Needles), Dressings, Convenience Kits.



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