

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

**Avanos Medical, Inc.**  
5405 Windward Parkway  
Alpharetta  
Georgia  
30004-3894  
USA

Holds Certificate Number:

FM 702907

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:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-03-01

Latest Revision Date: 2023-01-07

Effective Date: 2023-01-09

Expiry Date: 2026-01-08

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Effective

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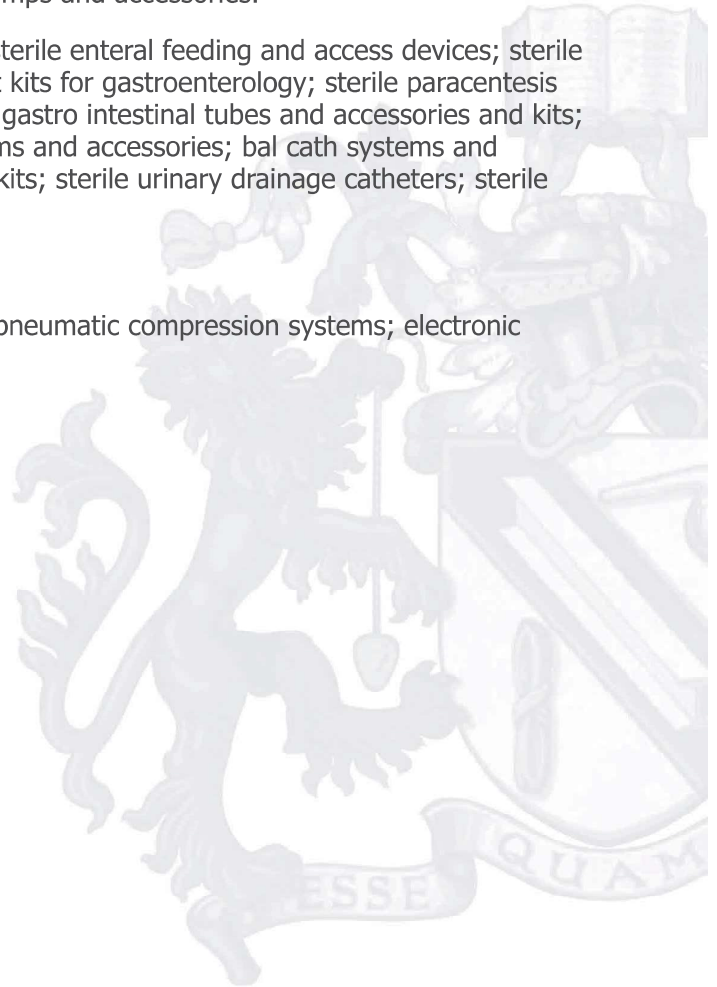
## Registered Scope:

Design, manufacture, and distribution of sterile pain management kits; sterile anesthesia conduction needles and kits; peripheral nerve stimulators, accessories for electronic stimulators, and nerve locators; disposable elastomeric, mechanical and syringe infusion pumps (non- electric); pump fillers; administration sets; catheters (including silver coated catheters); introducers (needles); dressings; intermittent pneumatic compression systems and accessories; RF Pain Management systems and accessories including generators, pumps, pressure monitoring devices, cannulas/introducers, cooled and non-cooled probes and tubing kits; pain management convenience kits, electronic infusion pumps and accessories.

Design, manufacture, and distribution of sterile and non-sterile enteral feeding and access devices; sterile respiratory care packs; saline vials; in vitro diagnostic test kits for gastroenterology; sterile paracentesis trays and kits; endotracheal tubes; sterile and non-sterile gastro intestinal tubes and accessories and kits; oral care kits; percussors; tracheal and oral suction systems and accessories; bal cath systems and endoscopic devices and accessories; enteral declogging kits; sterile urinary drainage catheters; sterile neonatal procedure drapes.

Distribution of microbial sealant.

Servicing of enteral feeding access systems; intermittent pneumatic compression systems; electronic infusion pumps.



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Contact Office: 12900 Middlebrook Drive, Suite 800, Herndon, VA 20170-5083, USA

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Location	Registered Activities
Avent S. de R.L. de C.V. Avenida Hidalgo #1 y Luis Donaldo Colosio Parque Industrial San Carlos Nogales Sonora 84092 Mexico	Receiving, purchasing and distribution.
Avanos Medical, Inc. 5405 Windward Parkway Alpharetta Georgia 30004-3894 USA	Design, manufacture, and distribution of sterile pain management kits; sterile anesthesia conduction needles and kits; peripheral nerve stimulators, accessories for electronic stimulators, and nerve locators; disposable elastomeric, mechanical and syringe infusion pumps (non- electric); pump fillers; administration sets; catheters (including silver coated catheters); introducers (needles); dressings; intermittent pneumatic compression systems and accessories; RF Pain Management systems and accessories including generators, pumps, pressure monitoring devices, cannulas/introducers, cooled and non-cooled probes and tubing kits; pain management convenience kits, electronic infusion pumps and accessories.  Design, manufacture, and distribution of sterile and non-sterile enteral feeding and access devices; sterile respiratory care packs; saline vials; in vitro diagnostic test kits for gastroenterology; sterile paracentesis trays and kits; endotracheal tubes; sterile and non-sterile gastro intestinal tubes and accessories and kits; oral care kits; percussors; tracheal and oral suction systems and accessories; bal cath systems and endoscopic devices and accessories; internal declogging kits; sterile urinary drainage catheters; sterile neonatal procedure drapes.  Distribution of microbial sealant.  Servicing of enteral feeding access systems; intermittent pneumatic compression systems; electronic infusion pumps.
Avent, Inc. 6620 S. Memorial Place, Suite 100 Tucson Arizona 85756 USA	The manufacture and distribution of: Pain Management (including Sterile Anesthesia products) kits and associated components; in vitro diagnostic test kits for gastroenterology, sterile and non-sterile gastro intestinal tubes, accessories and kits; sterile paracentesis trays and kits; oral care kits; accessories for peripheral nerve stimulators and nerve locators, tracheal and oral suction systems and accessories, and manufacture of catheters to add silver. The servicing and distribution of enteral feeding and access device.

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Location	Registered Activities
Avent S. de R.L. de C.V. Circuito Industrial No 40 Colonia Obrera Nogales CP 84048 Mexico	The manufacture and distribution of: Non Sterile and Sterile Enteral Feeding and Access Devices; Sample Collection Kits; sterile endotracheal tubes, sterile Pain Management Kits, Oral Care Kits and Oral Suction Accessories.
Avent S. de R.L. de C.V. Nogales II 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.
Avent S. de R.L. de C.V. Carretera Internacional Salida Norte 1053 Magdalena Sonora CP 84160 Mexico	The manufacture and distribution of 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.
Avanos Medical, Inc. 2170 Anntom Drive Dania Beach Florida 33312 USA	The servicing of intermittent pneumatic compression systems.
Avanos Medical, Inc. 4054 Pike Lane Concord California 94520 USA	The servicing of intermittent pneumatic compression systems.

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## Location

Avent S. de R.L. de C.V.  
Ave Noruega Edificio D-1B  
Fraccionamiento, Rubio  
Tijuana  
Baja California  
22116  
Mexico

## Registered Activities

Manufacture of Disposable and Reusable Elastomeric, Mechanical and Syringe Infusion Pumps (Non- Electric), Pump Fillers, Administration Sets, Catheters, Introducers (Needles), Dressing, Convenience Kits. Manufacture of cooled and non-cooled probes and accessories.

Manufacture of Pain Management (including Sterile Anesthesia products) kits and associated components; Sterile and Non-sterile Gastro Intestinal tubes and accessories and kits; Sterile Paracentesis Trays and Kits; and enteral declogging kits. Manufacture of electronic infusion pumps and accessories.

Manufacture of catheters, kits, silicone pumps and needles.

Manufacture of accessories for intermittent pneumatic compression systems, and electronic infusion pumps and accessories.

Receiving, Warehouse, Incoming Inspection, and Labeling.

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