



CERTIFICATE OF REGISTRATION

This is to certify that

DeRoyal Industries, Inc.

200 DeBusk Lane Powell , Tennessee 37849 USA

Refer to Attachment to Certificate of Registration dated August 24, 2018 for additional certified sites
operates a

Quality Management System

which complies with the requirements of

ISO 13485:2003

for the following scope of certification

Design, manufacture and distribution of Scalpels, Cautery pencils and blades, Surgical Sponges and dressings, Surgical Gauze Packing, Bandages, Surgical specimen Pouches, surgical Vessel Loops, surgical eye spears, Vaginal and Perineal packing for surgery, surgical insufflation filters and tubing, Pneumoperitoneum Needles, Surgical procedure trays. Design, manufacture and distribution of Wound Care Dressings and Kits, Umbilical cord clamps, High pressure lines, manifolds, stop cocks and syringes for angiography, Temperature Probes, Blood pressure cuffs, Esophageal Stethoscopes, Foley Catheters, Lubricants for patients, Defogger for endoscopy. Design, manufacture and distribution of procedure packs for surgical procedures and angio products and angio procedure trays. Design, manufacture and distribution of implantable orthopedic screws, plates and surgical instruments

Certificate No.: CERT-0075523
File No.: 025385

Original Certification Date: December 4, 2003
Certification Effective Date: March 23, 2018
Certification Expiry Date: December 31, 2018

Kevin Goodwin
General Manager Technical Services SAI Global Assurance



ISO 13485:2003



CMDCAS Recognized Registrar



Registered by:
QMI-SAI Canada Limited (SAI Global), 20 Carlson Court, Suite 200, Toronto, Ontario M9W 7K6 Canada. This registration is subject to the SAI Global Terms and Conditions for Certification. While all due care and skill was exercised in carrying out this assessment, SAI Global accepts responsibility only for proven negligence. This certificate remains the property of SAI Global and must be returned to them upon request.
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ATTACHMENT TO CERTIFICATE OF REGISTRATION

These sites are registered under Certificate No: CERT-0075523 issued on August 24, 2018

File No.

- 025385 **DeRoyal Industries, Inc.**
200 DeBusk Lane Powell , Tennessee 37849 USA
Processes covered at this location: Administration (sales and marketing, IT, supplier evaluation and purchase Quality Assurance and Regulatory Affairs (maintenance of QMS, internal audits, complaint handling, CAPA - corporate level); Design and Development Final Inspection: bulk non-sterile angio products.
- 025392 **DeRoyal Industries, Inc.**
DeRoyal Cientifica de Latinoamerica S.A.
Global Park P.O. Box 180-3006,602 Parkway La Aurora, Heredia , 146 Costa Rica
Dependent processes covered at this location: Administration (Management, Human Resources, Purchase); Quality Assurance and Quality Control; Warehouse (receiving, incoming inspection, storage, shipping); Manufacturing (production, inspection, calibration and maintenance); Products produced at the facility include: Cautery pens, Esophagel stethoscopes, temperature sensors.
- 026261 **DeRoyal Industries, Inc.**
Distribution Center
1755 Hwy. 33 South New Tazewell , Tennessee 37825 USA
Dependent processes covered at this location: Warehouse for incoming and finished goods; Internal and external shipping; Administration and logistics of goods; Quality Control
- 026262 **DeRoyal Industries, Inc.**
(Processing Center)
1703 Hwy. 33 South New Tazewell , Tennessee 37825 USA
Dependent processes covered at this location: Administration (Management); Quality Control; Manufacturing; Products produced at technologies includes: Canisters, canister holders, Skin Markers, Light Handle Covers, Defoggers, Tonsil Sponges, Self Adherent Bandages, Vessel Loops, Esmark Bandages, Cautery Tip Cleaners
- 1603310 **DeRoyal Industries, Inc.**
Manufacturing Center 1595
1595 Hwy 33 South New Tazewell , Tennessee 37825 USA
Dependent processes covered at this location: Administration & Management; Quality Control / QA; Manufacturing of Heel warmer, Multidex, Algidex, Foley Catheters, procedure packs.
- 1621891 **DeRoyal Industries**

These registrations are dependent on DeRoyal Industries, Inc. (File No. 025385) maintaining their scope of certification to ISO 13485:2003

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Royal Sterilization Systems

1135 Hwy 33 South New Tazewell , Tennessee 37825 USA

Dependent processes covered at this location: Management, Warehouse, QA, QC, ethylene oxide sterilization, laboratory services.

1621892

DeRoyal Industries Inc.

700 Martin Luther King Jr. Blvd. Sanford , Florida 32711 USA

Dependent processes covered at this location: Management and administration; Quality Assurance and Quality Control: Inspection of parts from DR; Warehouse; Purchasing; Maintenance and calibration; Manufacture: Injection molding of angio parts.

1621893

DeRoyal Industries Inc.

1501 East Central Ave. Lafollette , Tennessee 37766 USA

Dependent processes covered at this location: Quality Assurance and Quality Control; Administration; Design and Development (design of angio trays from finished devices); Manufacturing of angiography products and angiography kits.

1621897

DeRoyal Guatemala

Ortho and Surgical Products Enterprises S.A.

Km 20.5 carretera a Villa Canales, zona 3, Finca Morancito Villa Canales , Guatemala Guatemala

Dependent processes covered at this location: Management and Quality Control; Preventive maintenance and calibration; Manufacturing of subassemblies for medical devices, Manufacture of Surgical sponges, dressings, gauze packaging, specimen pouches, vaginal and perineal packaging, wound care dressings and kits

1621898

DeRoyal Intercontinental, S.L.R.

KM 7, Autopista Joaquin Balaguer Pisano Free Zone, Building 49 Santiago , Dominican Republic Dominican Republic

Dependent processes covered at this location: Management, Quality Control; Maintenance and Calibration; Manufacturing of subassemblies for medical devices, Manufacture of molded plastic, Surgical sponges, Anti Fog solutions, Angio products, Insufflation filters and Tubing's.

1621900

DeRoyal Industries, Inc.

164 Giles Hollow Road Rose Hill , Virginia 24281 USA

Dependent processes covered at this location: Quality Assurance and Quality Control;

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Administration; Manufacture of bandages and gauze.

1626609 **DeRoyal Industries, Inc.
(Converting)**
185 Richardson Way Maynardville , Tennessee 37807 USA

Dependent processes covered at this location: Management, manufacturing, warehouse, QA, QC;
Manufacture of wound dressings.

1626612 **DeRoyal Industries, Inc.
(Trauma)**
2341 W. Beaver creek Road Powell , Tennessee 37849 USA

Dependent processes covered at this location: Management and administration; Quality Assurance
and Quality Control; Maintenance and calibration; Design and Manufacture of implantable
orthopedic screws, plates and surgical instruments.

1689100 **DeRoyal Industries, Inc.
Royal Precision Plastics**
300 DeBusk Lane Powell , Tennessee 37849 USA

Management, QC, calibration, manufacturing, assembly, distribution, of non-active medical devices
with measuring function.

1694809 **DeRoyal Industries, Inc.
Hospital Disposables - Manufacturing**
104 Wheeler Street Portland , Tennessee 37148 USA

Manufacturing

1694810 **DeRoyal Industries, Inc.
Hospital Disposables - Warehouse**
136 Davis Street Portland , Tennessee 37148 USA

Warehouse

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