



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 October 2, 2017 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, 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 patiences, 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-0105801

File No.: 025385

Original Certification Date: December 4, 2003

Certification Effective Date: October 2, 2017

Certification Expiry Date: March 23, 2018

Nicole Grantham
General Manager SAI Global Certification Services



ISO 13485:2003



CMDCAS Recognized Registrar



ATTACHMENT TO CERTIFICATE OF REGISTRATION

These sites are registered under Certificate No: CERT-0105801 issued on October 2, 2017

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.**
Distribution Center
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.

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

ATTACHMENT TO CERTIFICATE OF REGISTRATION

These sites are registered under Certificate No: CERT-0105801 issued on October 2, 2017

- 1621891 **DeRoyal Industries
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 Canalaes, 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; Administration; Manufacture of bandages and gauze.

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

ATTACHMENT TO CERTIFICATE OF REGISTRATION

These sites are registered under Certificate No: CERT-0105801 issued on October 2, 2017

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.

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