



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 April 30, 2015 for additional certified sites

operates a

Quality Management System

which complies with the requirements of

ISO 13485:2003

for the following scope of registration

The registration covers the Quality Management System for 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-0075522

File No.: 025385

Original Date: December 4, 2003

Effective Date: April 30, 2015

Expiry Date: March 23, 2018

Chris Jouppi
President,
QMI-SAI Canada Limited

SamerChaouk
Head of Policy, Risk and Certification



CMDCAS Recognized Registrar



Registered by:

SAI Global Certification Services Pty Ltd, 286 Sussex Street, Sydney NSW 2000 Australia with SAI Global, 20 Carlson Court, Suite 100, 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.

To verify that this certificate is current, please refer to the SAI Global On-Line Certification Register: www.qmi-saiglobal.com/qmi_companies/

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INFORM. INSPIRE. IMPROVE.

ATTACHMENT TO CERTIFICATE OF REGISTRATION

These sites are registered under Certificate No: CERT-0075522 issued on April 30, 2015

File No.

025385

DeRoyal Industries, Inc.

200 DeBusk Lane, Powell, Tennessee 37849 USA

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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

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

1603310

DeRoyal Industries, Inc.

Manufacturing 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, Algindex, and Foley Catheters

026262

**DeRoyal Processing Center
(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

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

ATTACHMENT TO CERTIFICATE OF REGISTRATION

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File No.

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, angiography kits and procedure packs

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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

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.

1621897

Ortho and Surgical Products Enterprises S.A.

1a Avenida 6-70 Zona 1, Villa Canales, 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, eye spears, vaginal and perineal packaging, wound care dressings and kits

1621898

DeRoyal Industries, Inc.

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

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File No.

- 1621892 **DeRoyal Industries, Inc.**
700 Martin Luther King Jr. Blvd. Sanford, Florida, 32771, 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
- 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.
- 1626874 **DeRoyal Industries Inc.**
Textiles
125 East York Street, Camden, South Carolina 29020 USA
Dependent processes covered at this location:
- Management, manufacturing, purchasing, warehouse, QA, QC;
 - Manufacture of wound dressings.
- 1621891 **DeRoyal Industries**
Royal Sterilization Systems
1135 Hwy 33 South, New Tazewell, Tennessee 37825 USA
Dependent processes covered at this location:
- Management, Warehouse, QA
- 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.

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(File No. 025385) maintaining their scope of registration to ISO 13485:2003