



CERTIFICATE OF REGISTRATION

This is to certify that

DeRoyal Industries, Inc.

200 DeBusk Lane, Powell, Tennessee 37849 USA

D-U-N-S: 096372255

Refer to Attachment to Certificate of Registration dated December 17, 2018 for additional certified sites operates a

Quality Management System

which complies with the requirements of

ISO 13485:2016 and the requirements of the following regulatory authorities

Australia:

- Therapeutic Goods (Medical Devices) Regulations 2002: Schedule 3, Part 1 - Full Quality Assurance System

Brazil:

- RDC ANVISA n. 16/2013 - Good Manufacturing Practices
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009 - Vigilance

Canada:

- Medical Device Regulations SOR/98-282, Part 1

Japan:

- MHLW Ministerial Ordinance No.169 (2004) as amended by MHLW Ordinance No. 128 (2014) Articles 4 to 68
- Japan PMD Act (as applicable)

United States:

- 21 CFR Part 803 - Medical Device Reporting
- 21 CFR Part 806 - Reports of Corrections and Removals
- 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing
- 21 CFR Part 820 - Quality System Regulation

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.

Certificate No.: CERT-0126258

Original Certification Date: 2018-12-17

File No.: 025385

Certification Effective Date: 2018-12-17

Issue Date: 2018-12-17

Certification Expiry Date: 2021-12-16

Kevin Goodwin

General Manager Technical Services SAI Global Assurance



ISO 13485:2016

SAI Global is an MDSAP authorized auditing organization



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



ATTACHMENT TO CERTIFICATE OF REGISTRATION

These sites are registered under Certificate No: CERT- 0126258 issued on 2018-12-17

File No.		Effective Date
025385	<p>DeRoyal Industries, Inc.</p> <p>200 DeBusk Lane, Powell, Tennessee 37849 USA D-U-N-S: 96372255</p> <p>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.</p>	2018-12-17
025392	<p>DeRoyal Industries, Inc. DeRoyal Cientifica de Latinoamerica S.A.</p> <p>Global Park P.O. Box 180-3006,602 Parkway La Aurora, Heredia, 146 Costa Rica D-U-N-S: 853089571</p> <p>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, Esophageal stethoscopes, temperature sensors.</p>	2018-12-17
026261	<p>DeRoyal Industries, Inc. Distribution Center</p> <p>1755 Hwy. 33 South New Tazewell, Tennessee 37825 USA 1211 Hwy. 33 South New Tazewell, Tennessee 37825 USA 1615 Hwy. 33 South New Tazewell, Tennessee 37825 USA D-U-N-S: 080823398</p> <p>Dependent processes covered at this location: Warehouse for incoming and finished goods; Internal and external shipping; Administration and logistics of goods; Quality Control</p>	2018-12-17
026262	<p>DeRoyal Industries, Inc. (Processing Center)</p> <p>1703 Hwy. 33 South New Tazewell, Tennessee 37825 USA D-U-N-S: 080823398</p> <p>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</p>	2018-12-17
1603310	<p>DeRoyal Industries, Inc. Manufacturing Center 1595</p>	2018-12-17

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1595 Hwy 33 South New Tazewell, Tennessee 37825 USA
D-U-N-S: 883987091

Dependent processes covered at this location: Administration & Management; Quality Control / QA; Manufacturing of Heel warmer, Multidex, Algidex, Foley Catheters, procedure packs.

1621891 **DeRoyal Industries** 2018-12-17

Royal Sterilization Systems
1135 Hwy 33 South New Tazewell, Tennessee, 37825 USA
D-U-N-S: 825372873

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

1621892 **DeRoyal Industries Inc.** 2018-12-17

700 Martin Luther King Jr. Blvd. Sanford, Florida 32711 USA
D-U-N-S: 106859163

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.** 2018-12-17

1501 East Central Ave. Lafollette, Tennessee 37766 USA
D-U-N-S: 943656942

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** 2018-12-17

Ortho and Surgical Products Enterprises S.A.
Km 20.5 carretera a Villa Canales, zona 3, Finca Morancito Villa Canales,
Guatemala
D-U-N-S: 816178609

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.** 2018-12-17

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

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These sites are registered under Certificate No: CERT- 0126258 issued on 2018-12-17

D-U-N-S: 871483348

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.** 2018-12-17

164 Giles Hollow Road, Rose Hill, Virginia 24281 USA
D-U-N-S: 806016226

Dependent processes covered at this location: Quality Assurance and Quality Control; Administration; Manufacture of bandages and gauze.

1626609 **DeRoyal Industries, Inc. (Converting)** 2018-12-17

185 Richardson Way Maynardville, Tennessee 37807 USA
D-U-N-S: 118112630

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

1689100 **DeRoyal Industries, Inc. Royal Precision Plastics** 2018-12-17

300 DeBusk Lane, Powell, Tennessee 37849 USA
D-U-N-S: 801590811

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

1694809 **DeRoyal Industries, Inc. Hospital Disposables - Manufacturing** 2018-12-17

104 Wheeler Street Portland, Tennessee 37148 USA
D-U-N-S: 118112630

Manufacturing

1694810 **DeRoyal Industries, Inc. Hospital Disposables - Warehouse** 2018-12-17

136 Davis Street Portland, Tennessee 37148 USA
D-U-N-S: 830768941

Warehouse