

MANAGEMENT SYSTEM

CERTIFICATE

Certificate no.:
10000512270-PA-MDSAP-DNK

Initial certification date:
2018-12-17

Expiry Date:
2027-12-16

This is to certify that the management system of

DeRoyal Industries, Inc.

200 DeBusk Lane, Powell, Tennessee 37849 USA

F005805

and the sites as mentioned in the appendix accompanying this certificate [in case of multisite]

has been found to conform to the Quality Management System standard:

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

Australia:

- Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure
- Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 4 – Production Quality Assurance Procedure

Brazil:

- RDC ANVISA n. 665/2022
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009

Canada:

- Medical Devices Regulations – Part 1- SOR 98/282
- Medical Devices Regulations – Part 1.1 – SOR 98/282 (as applicable)

Japan:

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

United States:

- 21 CFR 803
- 21 CFR 806
- 21 CFR 807 – Subparts A to D

This certificate is valid for the following scope:

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 Negative Pressure Wound Therapy, 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. Waste Fluid Management. Design, manufacture and distribution of Procedure Packs for surgical procedures and Angio products and Angio Procedure Trays.

Place
Høvik

Effective Date:
2026-01-13



DNV Product Assurance AS is an MDSAP
Recognized Auditing Organization

For the issuing office:

DNV Product Assurance AS
Veritasveien 1, 1363 Høvik, Norway

Hazem Tinawi
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

ACCREDITED UNIT: DNV Product Assurance AS, Veritasveien 1, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

Your certificate is stored in DNV's secure certificate storage, providing traceability and trust to further enhance the value of your certification. Anyone can easily verify the validity of a certificate and details through the QR code on the certificate or in the link, <https://certificatechecker.dnv.com/> with the certificate number/manufacturer name.

Appendix to Certificate

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
DeRoyal Industries, Inc. F005805	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.
DeRoyal Cientifica de Latinoamerica S.R.L F005810	Global Park 602 Parkway La Aurora, Heredia Costa Rica 146	Dependent processes covered at this location: Administration (Management, Human Resources, Purchase); Quality Assurance and Quality Control; Warehouse (receiving, incoming inspection, storage, internal shipping and distribution); Manufacturing (production, inspection, calibration and maintenance); Products produced at the facility include: Cautery pencils, Esophageal stethoscopes, temperature sensors.
DeRoyal Industries, Inc. Distribution Center F005811	1755 Hwy 33 South, New Tazewell, Tennessee 37825 USA 1703 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.
DeRoyal Industries, Inc. Processing Center F005812	1703 Hwy 33 South, New Tazewell, Tennessee 37825 USA 1615 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, Angiography products and Safety Towels.
DeRoyal Industries, Inc. Manufacturing Center F005813	1595 Hwy 33 South, New Tazewell, Tennessee 37825 USA	Dependent processes covered at this location: Administration & Management; Quality Assurance and Quality Control; Manufacturing of Heel warmer, Multidex, Algidex, Foley Catheters, Negative Pressure Wound Therapy, Waste Fluid Management, Procedure packs & reprocessing
DeRoyal Industries, Inc. Royal Sterilization Systems F005814	1135 Hwy 33 South, New Tazewell, Tennessee 37825 USA 1211, Hwy 33 South, New Tazewell Tennessee 37825 USA	Dependent processes covered at this location: Management, Warehouse, Quality Assurance, Quality Control, ethylene oxide sterilization, laboratory services.
DeRoyal Industries, Inc. F005815	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.

Site Name	Site Address	Site Scope
Ortho and Surgical Products Enterprises S.A. (DeRoyal Guatemala) F005817	Km 20.5 carretera a Villa Canales, zona 3, Finca Morancito Villa Canales, Guatemala 01065	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 packing, specimen pouches, vaginal and perineal packing, wound care dressings and kits. Internal shipping and distribution.
DeRoyal Intercontinental, S.R.L. F005818	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. Internal shipping and distribution.
DeRoyal Industries, Inc. F005819	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 and procedure packs assembly.
DeRoyal Industries, Inc. Royal Converting F005820	185 Richardson Way, Maynardville, Tennessee 37807 USA	Dependent processes covered at this location: Management, manufacturing, warehouse, Quality Assurance and Quality Control; Manufacture of wound dressings.
DeRoyal Industries, Inc. Royal Precision Plastics F005821	300 DeBusk Lane, Powell, Tennessee 37849 USA	Management, Quality Control, calibration, manufacturing, assembly, distribution of non-active medical devices with measuring function.
DeRoyal Industries, Inc. International Distribution Center F005822	135 Richardson Way, Maynardville, Tennessee 37807 USA	Warehouse for incoming and finished goods; Internal and external shipping; logistics of goods.