

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
C838412

Initial certification date:
30 April 2019

Valid:
23 June 2026 – 30 April 2028

This is to certify that the management system of
DeRoyal Industries, Inc.
200 DeBusk Lane, Powell, TN, 37849, USA
and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:
ISO 13485:2016 / EN ISO 13485:2016

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, 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. Contract reprocessing of electrosurgical, cutting & coagulation accessories, laparoscopic & endoscopic devices.

Design, manufacture, and distribution of Orthotic products: Spine Bracing, Ankle Bracing, Knee Bracing, Elbow Bracing, Shoulder Bracing, Fracture Bracing and Walkers. Design, manufacture, and distribution of Orthopedic Soft goods: Cervical Collars and Traction, Clavicle Straps, Shoulder, Elbow and Knee Immobilizers, Arm Slings and Elevators, Elbow Support and Sleeves, Splints, Abdominal Binders and Belts, Supports, Post-op Shoes and Cast Shoes. Design, manufacture, and distribution of Patient Protection products: Limb Holders, Vests, Hand Control Mittens, Ankle Contracture Boots, Fall Prevention, Supports and Foam Positioners. Design, manufacture, and distribution of Rehabilitation products: Range of Motion and Splints. Design, manufacture, and distribution of Temperature Therapy products: Units, Blankets, and Thermal Wraps.

Ethylene oxide sterilization services of medical devices. The validation and routine control of a sterilization process as per ISO 11135:2014 requirements

Place and date:
Høvik, 09 July 2026



For the issuing office:
DNV Product Assurance AS
Veritasveien 1, 1363 Høvik, Norway

Cecilie Gudesen Torp

Cecilie Gudesen Torp
Management Representative

Appendix to Certificate

DeRoyal Industries, Inc.

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
DeRoyal Industries, Inc.	200 DeBusk Lane, Powell, TN, 37849, USA	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 Industries, Inc. Royal Precision Plastics	300 DeBusk Lane, Powell, TN, 37849, USA	Management, Quality Control, calibration, manufacturing, assembly, distribution of non-active medical devices with measuring function.
DeRoyal Industries, Inc. Distribution Center	1755 Highway 33 South, New Tazewell, TN, 37825, USA	Warehouse for incoming and finished goods; Internal and external shipping; Administration and logistics of goods; Quality Control.
	1703 Highway 33 South, New Tazewell, TN, 37825, USA	
DeRoyal Industries, Inc. Processing Center	1703 Highway 33 South, New Tazewell, TN, 37825, USA	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.
	1615 Highway 33 South, New Tazewell, TN, 37825, USA	
DeRoyal Industries, Inc. Royal Sterilization Systems	1135 Highway 33 South, New Tazewell, TN, 37825, USA	Management, Warehouse, Quality Assurance, Quality Control, Ethylene oxide sterilization services of medical devices. The validation and routine control of a sterilization process as per ISO 11135:2014 requirements and laboratory services for chemistry, microbiology, sterility and media preparation.
	1211 Highway 33 South, New Tazewell, TN, 37825, USA	
DeRoyal Industries Inc. Manufacturing Center	1595 Highway 33 South, New Tazewell, TN, 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 Intercontinental, S.R.L.	Km 7, Autopista Joaquin Balaguer, Pisano Free Zone, Building 49, Santiago, Dominican Republic	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. Royal Converting	185 Richardson Way, Maynardville, TN, 37807, USA	Management, manufacturing, warehouse, Quality Assurance and Quality Control; Manufacture of wound dressings

Site Name	Site Address	Site Scope
DeRoyal Industries, Inc. DeRoyal Cientifica de Latinoamerica S.R.L.	Global Park, 602 Parkway, 146, La Aurora Heredia, Costa Rica	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.
Ortho and Surgical Products Enterprises S.A. (DeRoyal Guatemala)	Km 20.5 carretera a Villa Canales, zona 3, Finca Morancito Villa Canales, Guatemala 01065	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.

