

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
10000500716-PA-NA-DNK

Initial certification date:
30 April 2019

Valid:
20 December 2025 – 30 April 2028

This is to certify that the management system of
DeRoyal Industries, Inc - HQ
200 DeBusk Lane, Powell, Tennessee 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, 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.

Place and date:
Høvik, 20 December 2025



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 - HQ

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
DeRoyal Industries, Inc - HQ	200 DeBusk Lane, Powell, Tennessee 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, Tennessee, 37849, USA	Management, Quality Control, calibration, manufacturing, assembly, distribution of non-active medical devices with measuring function.
DeRoyal Industries, Inc. - Distribution Center	1. 1755 Hwy 33 South, New Tazewell, Tennessee 37825 USA 2. 1703 Hwy 33 South, New Tazewell, Tennessee 37825 USA"	Warehouse for incoming and finished goods; Internal and external shipping; Administration and logistics of goods; Quality Control.
DeRoyal Industries, Inc. (Processing Center)	1. 1703 Hwy 33 South, New Tazewell, Tennessee 37825 USA 2. 1615 Hwy 33 South, New Tazewell, Tennessee 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.
DeRoyal Industries, Inc. - Royal Sterilization Systems	1. 1135 Highway 33 South, New Tazewell, TN, 37825, USA 2. 1211 Highway 33 South New Tazewell, TN 37825, USA	Management, Warehouse, Quality Assurance, Quality Control, Ethylene oxide sterilization of medical devices and laboratory services for chemistry, microbiology, sterility and media preparation
DeRoyal Industries, Inc. - International Distribution Center	135 Richardson Way, Maynardville, Tennessee 37807 USA	Warehouse for incoming and finished goods; Internal and external shipping; logistics of goods.
DeRoyal Industries Inc. - Manufacturing Center	1595 Highway 33 South, New Tazewell, TN, 37825, USA	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.	700 Martin Luther King Jr. Blvd., Sanford, Florida 32711 USA	Management and administration; Quality Assurance and Quality Control: Inspection of parts from DR; Warehouse; Purchasing; Maintenance and calibration; Manufacture: Injection molding of angio parts
DeRoyal Industries, Inc.	164 Giles Hollow Road, Rose Hill, Virginia, 24281, USA	Quality Assurance and Quality Control; Administration; Manufacture of bandages and gauze and procedure packs assembly.

Site Name	Site Address	Site Scope
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, Tennessee, 37807, USA	Management, manufacturing, warehouse, Quality Assurance and Quality Control; Manufacture of wound dressings.
DeRoyal Industries, Inc. - DeRoyal Cientifica de Latinoamerica S.R.L	Global Park 602 Parkway La Aurora, Heredia Costa Rica 146	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.