Quality System Certificate

Certificate No.:	Reference:	Date of issue:	Valid Until:	Initial date of issue:
DGM – 925	aur2a2408v1230f422	2025-04-29	2028-04-30	2019-04-30

This is to certify that the quality system of:

DeRoyal Industries, Inc.
200 DeBusk Lane
Powell, TN 37849
USA

fulfills the requirements in:

ISO 13485:2016

The certificate covers the following activities:

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.

The certificate is valid provided that the quality system continues to conform to the above-mentioned scope and provided that the company does not introduce substantial changes to the quality system without the approval of Presafe Denmark A/S. Certifications to DS/EN ISO 13485:2012, EN ISO 13485:2012, ISO 13485:2003, DS/EN ISO 13485:2016, EN ISO 13485:2016, ISO 13485:2016, DS/EN ISO 9001: 2015, EN ISO 9001:2015, and ISO 9001:2015 include the requirements of any applicable corrigendum. The quality system certificate is issued pursuant to Presafe Denmark A/S' terms and conditions for the certification of quality systems for medical devices.

Presafe Denmark A/S
Notified Body, Identification No. 0543
Tuborg Parkvej 8, 2900 Hellerup, Denmark

Geshaan Sayd
Authorized person

For Presafe Denmark A/S

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Additional site(s) covered by the certificate:

DeRoyal Industries, Inc.
200 DeBusk Lane
Powell, TN 37849
USA

DeRoyal Industries, Inc.
Royal Precision Plastics
300 DeBusk Lane
Powell, TN 37849
USA

DeRoyal Industries, Inc.
Distribution Center
1755 Hwy. 33 South
New Tazewell, TN 37825
USA

1607 Hwy. 33 South
New Tazewell, TN 37825
USA

1703 Hwy. 33 South
New Tazewell, TN 37825
USA

DeRoyal Industries, Inc.
(Processing Center)
1703 Hwy. 33 South
New Tazewell, TN 37825
USA

1615 Hwy. 33 South
New Tazewell, TN 37825
USA

DeRoyal Industries Inc.
Royal Sterilization Systems
1135 Hwy 33 South
New Tazewell, TN 37825
USA

1211 Hwy. 33 South
New Tazewell, TN 37825
USA

DeRoyal Industries, Inc.
International Distribution Centre
135 Richardson Way
Maynardville, TN 37807
USA

DeRoyal Industries, Inc.
Manufacturing Center
1595 Hwy 33 South
New Tazewell, TN 37825
USA

DeRoyal Industries Inc.
700 Martin Luther King Jr. Blvd.
Sanford, FL 32711
USA

DeRoyal Industries Inc.
1501 East Central Ave.
Lafollette, TN 37766
USA

DeRoyal Industries, Inc.
164 Giles Hollow Road
Rose Hill, VA 24281
USA

DeRoyal Industries, Inc.
Royal Converting
185 Richardson Way
Maynardville, TN 37807
USA

DeRoyal Industries, Inc.
DeRoyal Cientifica de Latinoamerica S.R.L
Global Park,602 Parkway La Aurora, Heredia,
Costa Rica 146

Ortho and Surgical Products Enterprises S.A.
(DeRoyal Guatemala)
Km 20.5 carretera a Villa Canales, zona 3
Finca Morancito Villa Canales
Guatemala 01065

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DeRoyal Intercontinental, S.R.L.
KM 7, Autopista Joaquin Balaguer Pisano Free
Zone, Building.49
Santiago
Dominican Republic