

Quality System Certificate

Certificate No.:
DGM – 925

Reference:
aur2a1902v840f422

Date of issue:
2019-04-30

Valid Until:
2022-04-30

Initial date of issue:
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.

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 Softgoods: 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


Heidi Jørgensen
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,
Tennessee 37849
USA

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

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

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

1211 Hwy. 33 South New Tazewell
Tennessee 37825
USA

DeRoyal Industries, Inc.
Hospital Disposables - Warehouse
136 Davis Street Portland
Tennessee 37148
USA

1615 Hwy. 33 South New Tazewell
Tennessee 37825
USA

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

DeRoyal Industries
Royal Sterilization Systems
1135 Hwy 33 South New Tazewell
Tennessee 37825
USA

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

DeRoyal Industries Inc.
1501 East Central Ave. LaFollette
Tennessee 37766
USA

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

DeRoyal Industries, Inc.
Hospital Disposables - Manufacturing
104 Wheeler Street Portland
Tennessee 37148
USA

DeRoyal Industries, Inc.
165 Richardson Way Maynardville
Tennessee 37807
USA

DeRoyal Industries, Inc.
(Converting)
185 Richardson Way Maynardville
Tennessee 37807
USA

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DeRoyal Industries, Inc.
DeRoyal Cientifica de Latinoamerica S.A.
Global Park P.O. Box 180-3006,602 Parkway La
Aurora, Heredia, 146
Costa Rica

DeRoyal Intercontinental, S.L.R.
Km7, Autopista Joaquin Balaguer Pisano Free Zone,
Building 18, Santiago
Dominican Republic (DR)

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

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