

# Quality System Certificate

Certificate No.:  
**DGM – 925**

Reference:  
**aur2a2401v1220f422**

Date of issue:  
**2024-02-21**

Valid Until:  
**2025-04-30**

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. 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

**Zeshaan 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

**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.**  
**International Distribution Centre**  
135 Richardson Way  
Maynardville, TN 37807  
USA

1607 Hwy. 33 South  
New Tazewell, TN 37825  
USA

**DeRoyal Industries, Inc.**  
**Manufacturing Center**  
1595 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.**  
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.**  
165 Richardson Way  
Maynardville, TN 37807  
USA

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

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

**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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