

This is to certify that the quality system of:

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

has been approved in conformity with the requirements of:


Annex II, section 3.2 - Full quality assurance system

of Council Directive 93/42/EEC concerning medical devices as amended and transposed into Danish law, excluding Annex II, section 4.

The certificate covers the following activities:

Design and manufacture of dressings, bandages, surgical sponges, light handle and equipment covers, anti-fog solutions, sponge counting systems, needle counters, surgical markers, vessel loops, electrosurgical pencils including electrosurgical accessories, disposable neutral electrodes, control syringes, pressure lines (pressure monitoring), angio manifolds & stopcocks, temperature probes, foley catheters (w. temperature sensor), esophageal stethoscope (w. temperature sensor), orthopaedic trauma implant plating systems, instrument holders, instrument clamps and pads, suture boots, retractor covers, insufflations tubing and filters, smoke evacuation system, umbilical cord clamps, medicinal cups, inflation device, vascular compression device, veress needle and suture closer device in IIb, IIa, Im & Is

This EC certificate is issued in accordance with Presafe Denmark A/S' terms and conditions of. Council Directive 93/42/EEC concerning medical devices and entitles the manufacturer to affix the CE mark. The certificate is based on successful audit of the manufacturer. The manufacturer is subject to periodical audits in accordance with the Directive.



Heidi Jørgensen
Authorized person

For Presafe Denmark A/S

Date of issue: 2018-01-04
Expires: 2019-08-07
Initial date of issue: 2004-05-10
Reference: aur2a1706v692f422

The following products in class IIb are covered by the certificate:

- Dressing, Multidex (Gel and powder)
- Silicone adhesive wound dressing
- Electrosurgical pencils and blades
- Electrosurgical Grounding Pad
- Temperature probes
- Foley Catheters (w. Temperature probe)
- Esophageal stethoscope (w. temperature probe)
- Orthopaedic Trauma Implant Plating Systems
 - Locking Distal Radius Plates
 - Locking and Non-Locking Compression Plates
 - Locking and Non-Locking T ,L and Y Plates
 - Locking and Non-Locking Reconstruction Plates
 - Non-Locking Buttress Plates
 - Locking and Non-Locking Tubular Plates
 - Locking Adaption Plates
 - Locking Condylar Plates
 - Cannulated Screws
 - Cortical Screws
 - Malleolar Screws
 - Cancellous Screws
 - Shaft Screws
 - Washers and Nuts
 - Locking Screws
 - Pelvic Screws
 - Bone Wires

Certificate number: DGM – 460
Certificate type: EC Certificate

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The following products in class IIa are covered by the certificate:

- Vaginal packaging
- Vessel Loops
- Suture Boots, Retractor covers
- Control syringes
- Veress needle
- Insufflation tubing & filter
- Wound Dressing, non-adherent
- Surgical sponges
- Angio Manifolds and Stopcocks
- Suture closer device

The following products in class Is are covered by the certificate:

- Instrument Holders
- Needle counters
- Sponge counting systems
- Surgical Markers
- Anti-Fog solutions
- Equipment covers
- Cautery tip cleaners
- Umbilical cord clamps
- Bipolar Cords
- Esmark bandages
- Stockinettes
- Instrument holders, clamps and pads
- Smoke evacuation systems
- Dressing, burn
- Dressing, films
- Dressing, absorbent
- Lines (pressure monitoring)
- Disposable Blood Pressure Cuffs
- Splash Stop
- Scope Warmer
- Electrosurgical cables
- Vascular compression device

The following product in class Im is covered by the certificate:

- Medicinal cups

The following product in class Im and Is is covered by the certificate:

- Disposable Inflation Device

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A DNV & NEMKO
COMPANY

With the following sites:

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

DeRoyal Industries, Inc.
1595 Highway 33 South
New Tazewell, TN 37825, USA

DeRoyal Industries, Inc.
1703 Highway 33 South
New Tazewell, TN 37825, USA

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

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

DeRoyal Intercontinental, S.R.L.
Acute Care
KM7, Autopista Joaquin Balaguer
Pisano Free Zone, Building # 49
Santiago, Dominican Republic

Hospital Disposables
104 Wheeler Street
Portland, TN 37148, USA

Royal Precision Plastics
300 DeBusk Lane
Powell, TN 37849, USA

DeRoyal Industries, Inc.
1755 Highway 33 South
New Tazewell, TN 37825 USA

DeRoyal Cientifica De Latinoamerica S.A.
Global Park, Box 180-3006
602 Parkway
La Aurora Heredia, 146 Costa Rica

DeRoyal Industries, Inc.
2341 W. Beaver Creek Road
Powell, TN 37849, USA

DeRoyal Industries, Inc.
700 Martin Luther King Jr. Blvd.
Sanford, FL 32771, USA

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

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

Hospital Disposables
136 Davis Street
Portland, TN 37148, USA

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A DNV & NEMKO
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The authorized EC representative:

QNET BV
Hommerterweg 286
6436 AM Amstenrade
The Netherlands

COPY

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