



EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding section 4

Certificate No.:
DGM – 460

Reference:
aur2a2003v1130f422

Date of issue:
2020-08-26

Valid Until:
2024-05-26

Initial date of issue:
2004-05-10

This is to certify that the quality system of:

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

has been audited under the requirements of:

Annex II, Full quality assurance system, excluding section 4, of Council Directive 93/42/EEC as transposed into Danish law. The quality system meets the requirements of the MDD, Annex II.

The certificate covers the following devices:


Design and manufacture of dressings, bandages, surgical sponges, light handle and equipment covers, anti-fog solutions, 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), instrument holders, instrument clamps and pads, suture boots, insufflations tubing and filters, smoke evacuation system, umbilical cord clamps, medicinal cups, veress needle, suture closer device and measurement canister in IIb, IIa, Im & Is.

The EC certificate is valid provided that the quality system continues to conform to the above-mentioned scope and provided that the manufacturer does not introduce substantial changes to the quality system without the approval of Presafe Denmark A/S.

This EC certificate is issued in accordance with Presafe Denmark A/S' "General terms and conditions" cf. 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 MDD, Annex II, section 5.

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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The following product(s)/product families in class IIb are covered by the certificate:

Product family	GMDN code
Dressing, Multidex (Gel and powder)	46855
Silicone adhesive wound dressing	46854
Electrosurgical pencils and blades	61874
Temperature probes	35254
Foley Catheters (w. Temperature probe)	46629
Esophageal stethoscope (w. temperature probe)	44120

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

- Vessel Loops
- Suture Boots,
- 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
- 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)
- Splash Stop
- Scope Warmer
- Electrosurgical cables

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

- Medicinal cups
- Critical measurement canister



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Additional site(s) covered by the certificate:

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

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

DeRoyal Industries, Inc.
1595 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.
1703 Highway 33 South
New Tazewell, TN 37825, USA

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

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

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

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

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

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

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

International Distribution Center
135 Richardson Way
Maynardville, TN 37807, USA

The authorized EC representative:

QNET BV
Kantstraat 19
NL-5076 NP Haaren
The Netherlands