APPENDIX TO EC CERTIFICATE

Appendix to Certificate no.:
10000408810-PA-NA-DNK Rev 0.0

Valid Until:
26 May 2024

This is an Appendix issued to EC Certificate issued for manufacturer:
DeRoyal Industries, Inc.

originally issued in compliance with:
the Council Directive 93/42/EEC on Medical Devices, as amended

Based on assessment performed, the following changes to the certification has been accepted as compliance with Council Directive 93/42/EEC on Medical Devices has been established.

Address of one site has been corrected

Sites covered by certificate (replaces information on certificate)	
Site Name	**Site Address**
DeRoyal Intercontinental, S.R.L	KM 7, Autopista Joaquin Balaguer, Pisano Free Zone, Building 49 Santiago, Dominican Republic

Appendix History -		
Revision	**Description**	**Issued Date**
0.0	Editorial change of address to one of the sites	13 January 2022

Place and date:
Høvik, 13 January 2022

For the issuing office:
DNV Product Assurance AS - Notified Body 2460
Veritasveien 3, 1363 Høvik, Norway

Tone Elise Kolpus
Lead Auditor

DNV·GL

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
10000408810-PA-NA-DNK Rev 0.0	PRJN-197554-2020-PA-DNK	26 May 2024

This is to certify that the quality system of:

DeRoyal Industries, Inc.

200 DeBusk Lane, Powell, TN 37849, USA

For design, production and final product inspection/testing of:

DRESSINGS, NEGATIVE PRESSURE WOUND THERAPY PRODUCTS, BANDAGES, SURGICAL SPONGES, LIGHT HANDLE AND EQUIPMENT COVERS, ANTI-FOG SOLUTIONS, NEEDLE COUNTERS, SURGICAL MARKERS, VESSEL LOOPS, ELECTROSURGICAL PENCILS INCLUDING ELECTROSURGICAL ACCESSORIES, CONTROL SYRINGES, PRESSURE LINES (PRESSURE MONITORING), ANGIO MANIFOLDS & STOPCOCKS, TEMPERATURE PROBES, FOLEY CATHETERS WITH AND WITHOUT TEMPERATURE SENSOR, ESOPHAGEAL STETHOSCOPE WITH 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.

Has been assessed with respect to:

THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES, AS AMENDED

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 13 November 2020

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Eugenie Winger Husebye

Eugenie Winger Husebye

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

Certificate No.:
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Project No.:
PRJN-197554-2020-PA-DNK

Valid Until:
26 May 2024

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Transfer of Presafe Denmark A/S (NB 0543) Certificate No. DGM -460 to DNV GL Presafe A/S (NB2460)	13 November 2020

Products covered by this Certificate:

Product Description	Product Name	Class
Wound Dressing	Multidex (Gel and Powder) Silicone adhesive wound dressing	IIb
Foam for filling wound bed during Negative pressure wound therapy	Black foam	
Electrosurgical devices	Electrosurgical pencils and blades	
Temperature sensors	Temperature Probes	
Urinary Catheters	Foley Catheters with and without Temperature sensor	
Esophageal Stethoscope	Esophageal stethoscope with Temperature sensor	
Vessel closure devices	Vessel Loops	IIa
Protectors for surgical forceps	Suture Boots	
Angiographic devices	Control syringes Angio Manifolds Angio Stopcocks	
laparoscopic Instruments	Veress needle SutureClose	
Wound Dressing	non-adherent Wound Dressing	
Surgical sponge	Surgical sponges	
Insufflation devices	Insufflation tubings Insufflation filters	
Instrument holders	Instrument Holders Instrument Pads	Is
Surgical Needle counters	Needle Counters	
Surgical markers	Surgical Markers	

Anti-Fog solutions for endoscopes	Anti-Fog solutions	
Endoscopic Scope warmer	Scope Warmer	
Sterile covers	Light handle cover Equipment covers	
Cautery tip cleaners	Cautery tip cleaners	
Umbilical cord clamps	Umbilical cord clamps	
Cords	Bipolar Cords Electrosurgical cables	
Bandages	Esmark bandages Stockinettes	
Smoke evacuation systems components	Attachment for cautery pencil Adapter for smoke evacuation filter	
wound Dressing	Dressing, burn Dressing, films Dressing, absorbent	
Waste Fluid Management Product	Splash Stop	
Pressure monitoring tubing	Lines (pressure monitoring)	
Negative pressure Dome Connectors	Dome Connectors	
Devices for volumen measurements	Medicinal cups Critical measurement canister	Im

The complete list of devices is filed with the Notified Body

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Valid Until:
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Sites covered by this certificate

Site Name	Address
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	185 Richardson Way, Maynardville, TN 37807, USA
DeRoyal Industries, Inc	700 Martin Luther King Jr. Blvd., Sanford, FL 32771, USA
DeRoyal Industries, Inc	1501 East Central Ave., Lafolette, TN 37766, 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.	KM 20.5 Carretera A Villa Canales Zona 3 Finca Morancito, Villa Canales Guatemala, GT 01065
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

EU Representative
Emergo Europe, Prinsessegracht 20, 2514 AP The Hague, The Netherlands

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Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate