EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
10000319843-PA-NA-IND	PRJC-139241-2009-MSL-IND	27 May 2024

This is to certify that the quality system of:

Ribbel International Ltd.

20th Mile, P.O. Rai, Jatheri Road, Sonepat – 131029, Haryana, India

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

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, 03 November 2020

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Alessandra Rinna

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

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.
NOTIFIED BODY: DNV GL PRESAFE AS, Veritasveien 3, N-1363 Høvik, Norway - Registered Enterprise No: NO 997 067 401 MVA .

Certificate No.:
10000319843-PA-NA-IND

Project No.:
PRJC-139241-2009-MSL-IND

Valid Until:
27 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	Original Certificate	03 November 2020

Products covered by this Certificate:

Product Description	Product Name	Class
Surgical Blades (Sterile)	Small Fitment Surgical Blade: fitment 3, blade size 9 to 17 Large Fitment Surgical Blade: : Fitment 4, blade size 18to 36D Large Fitment Surgical Blade: Fitment 8, blade size 60, 60B, 70 Miniature Fine Surgical Blades: Blade size 61 to 69 Myringotomy Blades: Standard	IIa
Surgical Skin Grafting Knife Blades (Sterile)	Surgical Skin Grafting Knife Blades Small and long Blade types: Dermatome blade long 158 mm Dermatome blade 110 mm Dermatome blade 80 mm Dermatome blade 75/50/25 mm Dermatome blade 63 mm Double cut disposable skin graft blade 63 mm with handle	IIa
Surgical Stich cutters (Sterile)	Stitch cutter Mini Stitch cutter Short Stitch cutter Standard Stitch cutter Long Stitch cutter Mini with handle	IIa
Disposable Scalpels (Sterile)	Disposable scalpel of small fitment: Fitment type 3 Disposable scalpel of Large fitment: Fitment type 4,6 and 8	IIa

	Disposable thumb/mini/short scalpel of small fitment: Fitment type 3 Disposable thumb/mini/short scalpel of large fitment: Fitment type 4, 6 and 8	
Disposable Safety Scalpels (Sterile)	Small fitment type: blade size 10 to 17 Large fitment type: blade size 18 to 25A	IIa
Foley Balloon Catheters (Sterile)	Foley Balloon Catheters 2 way: Size 6 FR to 30 FR Foley Balloon Catheters 3 way: Size 16 FR to 24 FR Foley Balloon Catheters 2 way Female: Size 12 FR to 24 FR	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	**Address**
Ribbel International Ltd.	20th Mile, P.O. Rai, Jatheri Road, Sonepat – 131029, Haryana, India

EU Representative
OBELIS S.A, Bd. Général Wahis, 53 1030 Brussels, Belgium.

Certificate No.:	Project No.:	Valid Until:
10000319843-PA-NA-IND	PRJC-139241-2009-MSL-IND	27 May 2024

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