

EC Certificate Full Quality Assurance System

Certificate No.:
245995-2017-CE-IND-NA-PS Rev. 0.0

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

Valid Until:
05 March 2019

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:

**Sterile & Non Sterile Carbon Steel & Stainless Steel Surgical
Blades, Skin Grafting Blades, Scalpels, Biopsy Punches, Blood
Lancets and Ophthalmic Blades & Knives**

Has been assessed with respect to:

**The conformity assessment procedure described in Article 11.3.a
and Annex II excluding section 4 (Module H2) 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, 29 September 2017



For:
DNV GL NEMKO PRESAFE AS

Alessandra Rinna

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

EC Certificate

Full Quality Assurance System

Certificate No.:
245995-2017-CE-IND-NA-PS Rev. 0.0

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

Valid Until:
05 March 2019

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	Supersedes DNVGL (NB 0434) Certificate no: 56886-2009-CE-IND-NA 3.0 following transfer to notified body functions to DNV GL Nemko Presafe AS (NB 2460)	2017-09-29

Products covered by this Certificate:

Product Description	Product Name	Class
Disposable Surgical Blades (Sterile & Non Sterile)	<ul style="list-style-type: none"> 1G, 2G, 3G, 4G, 5G, 8G, 9, 10, 10A, 10B, 10G, 10S, 11, 11K, 11P, 12, 12B, 12 D, 12G, 13, 14, 15, 15A, 15B, 15C, 15G, 15T, 16, 17, 18, 19, 20, 21, 22, 22A, 22B, 23, 24, 25, 25A, 26, 27, 36, 36D, 60, 60B, 61, 62, 63, 64, 65, 65A, 67, 67A, 68, 69, 70, 81, 82, 83, 84, 86, 88, 312, 313, 314, 316, PM40, PM40B, Myringotomy, Preparatory, Microtome 	IIa
Disposable Dermatome Blades	<ul style="list-style-type: none"> Deca / Davis Type, Padgett Type 	IIa
Disposable Skin Grafting Blades	<ul style="list-style-type: none"> Small (with or without Handles), Long 	IIa
Disposable Stitch Cutters	<ul style="list-style-type: none"> Mini (with or without Handles), Standard, Medium & Long 	IIa
Disposable Scalpels	<ul style="list-style-type: none"> Thumb / Mini, Long 1G, 2G, 3G, 4G, 5G, 8G, 9, 10, 10A, 10B, 10G, 10S, 11, 11K, 11P, 12, 12B, 12 D, 12G, 13, 14, 15, 15A, 15B, 15C, 15G, 15T, 16, 17, 18, 19, 20, 21, 22, 22A, 22B, 23, 24, 25, 25A, 26, 27, 36, 36D, 60, 60B, 70 	IIa
Disposable Safety Scalpels	<ul style="list-style-type: none"> 10, 10A, 10B, 10S, 11, 11K, 11P, 12, 12B, 12D, 13, 14, 15, 15A, 15B, 15C, 15T, 16, 17, 18, 19, 20, 21, 22, 22A, 22B, 23, 24, 25, 25A 	IIa
Blood Lancets	<ul style="list-style-type: none"> Standard 	IIa
Biopsy Punches	<ul style="list-style-type: none"> 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 5.0, 6.0 & 8.0 mm 	IIa
Ophthalmic Blades & Knives	<ul style="list-style-type: none"> Ultra-Thin Clear Cornea Blades – Round Stock (19G) Straight Bi-bevel & Angled Bi-bevel in 2.65mm, 2.8mm, 3.0mm, 3.2mm Sizes MVR Blades – Round Stock (19G, 20G, 24G) 	IIa

EC Certificate

Full Quality Assurance System

Certificate No.:
245995-2017-CE-IND-NA-PS Rev. 0.0

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

Valid Until:
05 March 2019

	<p>Straight and Angled</p> <ul style="list-style-type: none"> ▪ Sharp Tip Keratomes - Round Stock (19G) Straight Single Bevel, Straight Bi-bevel, Angled Bevel Up, Angled Bevel Down & Angled Bi-bevel in 2.5mm, 2.65mm, 2.8mm, 3.0mm, 3.2mm, 3.5mm Sizes ▪ Tunnel (Crescent) Blades – Round Stock (20G) Straight Single Bevel, Straight Bi-bevel, Angled Bevel Up, Angled Bevel Down & Angled Bi-bevel ▪ Lance Tip Blades – Round Stock (24G) Straight, Angled Right, Angled Left in 15 Degree, 30Degree & 45Degree ▪ Blunt Tip Keratomes – Flat Stock Straight Single Bevel, Angled Bevel Up, Angled Bevel Down in 3.8mm, 4.0mm, 4.5mm, 5.2mm, 5.5mm, 6.2mm, 6.7mm, 7.2mm Sizes ▪ Blunt Tip Keratomes – Round Stock Straight Single Bevel, Angled Bevel Up, Angled Bevel Down in 16G 3.8mm, 4.0mm, 5.0mm, 5.1mm, and 15G 5.5mm, 6.0mm, 6.2mm Sizes ▪ Sharp Tip Keratomes - Flat Stock Straight Single Bevel, Straight Bi-bevel, Angled Bevel Up, Angled Bevel Down & Angled Bi-bevel in 1.5mm, 2.5mm, 2.65mm, 2.8mm, 3.0mm, 3.2mm, 3.5mm, 5.2mm Sizes 	
--	---	--

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Ribbel International Limited	20 th Mile, P.O. Rai, Jatheri Road, Sonapat – 131029, Haryana, India.

EU Representative

Obelis s.a. Bd, General Wahis, 53 1030, Brussels, Belgium.

EC Certificate

Full Quality Assurance System

Certificate No.:
245995-2017-CE-IND-NA-PS Rev. 0.0

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

Valid Until:
05 March 2019

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