DET NORSKE VERITAS

FULL PRODUCT QUALITY MANAGEMENT CERTIFICATE - EC

Certificate No. 56886-2009-CE-IND-NA Rev. 2.0
This Certificate consists of 4 pages

This is to certify that the Quality Management System of

Ribbel International Ltd.

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

for production and final product inspection/testing of

Sterile & Non Sterile Stainless Steel & Carbon 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 H) of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

Further details are given overleaf

Place and date:
Høvik, 19 August 2009

For DET NORSKE VERITAS AS
Norway

Marianne Spæren
Certification Manager

NORWEGIAN ACCREDITATION
PROD 002

CE

Notified Body No.:
0434

This Certificate is valid until:
05 March 2014

Aud Løken Eiklid
Technical Reviewer

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

EU Representative

Obelis s.a.
Av. de Tervuren 34
BTE44, B-1040 Brussels
Belgium

Jurisdiction

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

Certificate history

Revision	Description	Issue Date
0	Original certificate	1998-11-24
1.0	First recertification	2004-03-05
2.0	**Second recertification**	**2009-08-19**

Products covered by this Certificate

Product Description	Product Name	Class
Disposable Surgical Blades (Sterile & Non Sterile)	▪ 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, 15T, 16, 17, 18, 19, 20, 21, 22, 22A, 22B, 23, 24, 25, 26, 27, 36, 36D, 60, 60B, 61, 62, 63, 64, 65, 65A, 67, 68, 69, 70, PM40, PM40B, Myringotomy, Preparatory, Microtome	IIa
Disposable Dermatome Blades	▪ Deca Type, Davis Type, Padgett Type	IIa
Disposable Skin Grafting Blades	▪ Small, Long	IIa
Disposable Stitch Cutters	▪ Mini, Standard, Medium & Long	IIa
Disposable Scalpels	▪ 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, 15T, 16, 17, 18, 19, 20, 21, 22, 22A, 22B, 23, 24, 25, 26, 27, 36, 36D, 60, 60B, 70	IIa
Disposable Safety Scalpels	▪ 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	IIa
Blood Lancets	▪ Standard	IIa
Biopsy Punches	▪ 1.0, 2.0, 2.5, 3.0, 3.5, 4.0, 5.0, 6.0 & 8.0 mm	IIa
Ophthalmic Blades & Knives	▪ 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) Straight and Angled ▪ Sharp Tip Keratomes - Round Stock (19G) Straight Single Bevel, Straight Bi-bevel, Angled Bevel Up, Angled Bevel	IIa

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 the local DNV Office of any intended updating of the quality system and DNV 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 DNV 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 DNV.

END OF CERTIFICATE