

DNV BUSINESS ASSURANCE

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 77668-2010-CE-IND-NA Rev 3.0

This Certificate consists of 3 pages

This is to certify that the Quality Management System of

Paramount Surgimed Ltd.

H.O.: 1, L.S.C., Okhla Industrial Area, Phase – II, New Delhi – 110 020, India.

Works: A-106, RIICO Industrial Area, Bhiwadi – 301 019, District Alwar, Rajasthan, India.

for design, production and final product inspection/testing of

Surgical Disposable Medical Devices

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, 16 February 2015

This Certificate is valid until:

18 February 2020

For DNV GL Business Assurance
Norway AS



Mariann Jeremiassen

Certification Manager

Notified Body No.:
0434

Cecilie Gudesen Torp

Technical Reviewer



This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info.

ATTESTED

K. Mathotra
Executive

PHD Chamber of Commerce and Industry

Notice: The certificate is subject to terms and conditions overleaf. Any significant changes in design or construction may render this certificate invalid. If any person is proved to have been caused by any negligent act or omission of Det Norske Veritas, then Det Norske Veritas shall pay compensation to such person for his proved direct loss or damage. However, the compensation shall not exceed an amount equal to four times the fee charged for the service in question, provided that the maximum compensation shall never exceed USD 300,000. In this provision "Det Norske Veritas" shall mean the Foundation Det Norske Veritas as well as all its subsidiaries, directors, officers, employees, agents and any other acting on behalf of Det Norske Veritas.

Det Norske Veritas AS, Veritasveien 1, 1322 Høvik, Norway. Tel: +47 67 57 9900 Fax: +47 6757 9911 www.dnv.com

Certified copy
For Paramount Surgimed Ltd.

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(Authorised Signatory)

CONSULADO DE CHILE EN
NUEVA DELHI, INDIA

El Cónsul de Chile que suscribe, certifica la
autenticidad de la firma de don.....Pushpa Ranjan.....
funcionario para asuntos consulares del Ministerio
de Relaciones Exteriores de India.

Actuación No. 1988..... Arancel Art No. 4/10

Derechos percibidos: US \$ 12.....

NUEVA DELHI.....16 de Junio de 2015

DERECHOS PAGADOS.....	<u>12</u>
COMPROB.DE PAGO No.....	<u>1</u>
ACT. No. <u>1988</u>	ART..... <u>4</u>No..... <u>10</u>

GUSTAVO A. CANTUARIAS CONCHA
Cónsul de Chile



5	LEGALIZADA EN EL MINISTERIO DE RELACIONES EXTERIORES DE CHILE
FIRMA DEL Sr. (a) <u>Gustavo Cantuarias</u>	
17 JUL 2015	
Patricia LÓPEZ RODRÍGUEZ Oficial de Legalizaciones	

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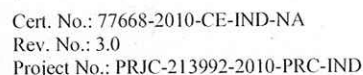
दिनांक

Date.....

वाणिज्य मंत्रालय में सहायक सचिव/उप सचिव/
सचिव के हस्ताक्षर सत्यापित किए जाते हैं।
The Signature of Asstt. Secretary/
Dy. Secretary/Secretary of Chamber
of Commerce Attested.



(पुष्पा रंजन)
(PUSHPA RANJAN)
अनुयाग अधिकारी (सत्यापन)
Section Officer (Attestation)
सी.पी.वी. प्रभाग/C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs
New Delhi



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.

Revision	Description	Issue Date
	Original certificate	2005-02-18
	Recertification	2010-02-18
1.0	Editorial revision of addresses	2010-07-20
2.0	Size Addition	2014-02-11
3.0	Recertification	2015-02-18

Product Description	Product	Class
Surgical Blades (Sterile & Non-Sterile) in Carbon Steel & Stainless Steel	Sizes: 1, 2, 3, 4, 5, 6, 8, 9, 10, 10A, 11, 11K, 12, 13, 14, 15, 15B, 15C, 15D, 15S, 16, 17, 18, 19, 20, 21, 22, 22A, 23, 24, 25, 36, 40, 40B, 60, 60B, 61, 62	IIa
Disposable Scalpels in Carbon Steel & Stainless Steel	Sizes: 1, 2, 3, 4, 5, 6, 8, 9, 10, 10A, 11, 11K, 12, 13, 14, 15, 15B, 15C, 15D, 15S, 16, 17, 18, 19, 20, 21, 22, 22A, 23, 24, 25, 36	IIa
Safety Scalpels in Carbon Steel & Stainless Steel	Sizes: 6, 9, 10, 10A, 11, 11K, 12, 13, 14, 15, 15B, 15C, 15D, 15S, 16, 17, 18, 19, 20, 21, 22, 22A, 23, 24, 25, 36	IIa
Stitch Cutters	Long, Short, Mini	IIa
Skin Graft Blades	Simplex, Duplex	IIa
Blood Lancet	Standard	IIa
Biopsy Punches	1mm, 1.5mm, 2mm, 2.5mm, 3mm, 3.5mm, 4mm, 5mm, 6mm, 7mm, 8mm, 10mm, 12mm	IIa
Curette Dermal	2mm, 3mm, 4mm, 5mm, 7mm	IIa
Ophthalmic Blades	Keratome: P-912301, P-912501, P-912601, P-912801, P-912901, P-913201, P-91350, P-915001, P-912361, P-912561, P-912661, P-912861, P-912961, P-913261, P-913561, P-915061, P-912808, P-912908, P-913208, P-912868, P-912968, P-913268, P-914001, P-915201, P-915501, P-916001, P-916201, P-914061, P-915161, P-915561, P-916061, P-916261 Crescent: P-950001, P-950002, P-950003, P-950004, P-950005 Lance Tip: P-931501, P-933001, P-934501 MVR: P-975559, P-975560, P-975561, P-983500, P-983501	IIa



HEAD OFFICE: Det Norske Veritas AS, Veritasveien 1, 322 Havik, Norway. Toll: +47 67 57 9900 Fax: +47 67 57 9911 www.dnv.com

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(Authorised Signatory)

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01 JUN 2015

सत्यापित दिनांक
No. Date

वाणिज्य सचिव के सहायक सचिव/उप सचिव/
सचिव के हस्ताक्षर सत्यापित किए जाते हैं।
The Signature of Asstt. Secretary/
Dy. Secretary/Secretary of Chamber
of Commerce Attested.



(पुष्पा रंजन)
(PUSHPA RANJAN)
अनुभाग अधिकारी (सत्यापन)
Section Officer (Attestation)
सी.पी.वी. विभाग/C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs
New Delhi





Cert. No.: 77668-2010-CE-IND-NA
Rev. No.: 3.0
Project No.: PRJC-213992-2010-PRC-IND

	Spoon: P-6820, P-6821, P-6821E	
	Scleral: P-5700, P-5710	

The complete list of devices is filed with the Notified Body.

Sites covered by this certificate

Site Name	Address
Paramount Surgimed Limited	H.O.: 1, L.S.C., Okhla Industrial Area, Phase – II, New Delhi – 110 020, India. Works: A-106, RIICO Industrial Area, Bhiwadi – 301 019, District Alwar, Rajasthan, India

EU Representative

Medical Device Safety Service GmbH, Schiffgraben 41, D-30175, Hannover, Germany.

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



Certified True Copy
For Paramount Surgimed Ltd.
(Authorised Signatory)

ATTESTED

S.K. Malhotra
Executive

PHD Chamber of Commerce and Industry
New Delhi-110014 (INDIA)

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01 JUN 2015

संख्या दिनांक
No. Date
वाणिज्य मंत्रालय में सहायक सचिव/उप सचिव/
सचिव से हस्ताक्षर सत्यापित किए जाते हैं।
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विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs
New Delhi

ATTESTED

Executive

PHD Chamber of Commerce and Industry

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