DNV·GL

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.	Valid Until:
10000400574-PA-NA-IND	PRJC-213992-2010-PRC-IND	27-05-2024

This is to certify that the quality system of:

Paramount Surgimed Ltd.

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

For design, production and final product inspection/testing of:
STERILE SURGICAL 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, 15 September 2020

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Mariann Jeremiassen

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

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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	2020-09-15

Products covered by this Certificate:

Product Description	Product Name	Class
Sterile Curette Dermal	Curette Dermal Size: 2, 3, 4, 5 & 7	IIa
Sterile Stitch cutters in Carbon Steel and Stainless Steel	Stitch Cutters Long, Short, Mini	IIa
Sterile Surgical Blades in Carbon Steel and Stainless Steel	Surgical blades 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,1R, 2R, 3R, 1V, 2V, 3V, 11P, 12D, 24D, 34, 36D	IIa
Sterile Disposable Scalpels in Carbon Steel and Stainless Steel	Disposable Scalpels 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, 36,1R, 2R, 3R, 1V, 2V, 3V, 11P, 12D, 24D, 34, 36D	IIa
Sterile Safety Scalpels in Carbon Steel and Stainless Steel	Safety Scalpels 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, 1R, 2R, 3R, 1V, 2V, 3V,11P, 12D, 24D, 34, 36D	IIa
Sterile Fine Blades / Chisel Blade / Microsurgery blades	61, 62, 63, 64, 65, 66, 67, 68, 69, 69B, 61V, 62V, 90, 91	IIa
Sterile Ophthalmic Blades	Keratome: P-912301, P-912501, P-912601, P-912801, P912901, P-913201, P-913501, P-915001, P-912361, P912561, P-912661, P-912861, P-912961, P-913261, P913561, P-915061, P-912808, P-912908, P-913208, P912868, P-912968, P-913268, P-914001, P-915201,	IIa

	P915501, P-916001, P-916201, P-914061, P-915161, P915561, P-916061, P-916261 Crescent: P-950001, P-950002, P-950003, P-950004, P950005 Lance Tip: P-931501, P-933001, P-934501, P-913501, P915101, P-915161, P-914101, P-914161, P-915261 MVR: P-975559, P-975560, P-975561, P-985560, P 985561 Spoon: P-6820, P-6821, P-6821E Scleral: P-5700, P5710	
Sterile Biopsy Punches	Biopsy Punches: 1mm, 1.5mm, 2mm, 2.5mm, 3mm, 3.5mm, 4mm, 5mm, 6mm, 7mm, 8mm, 10mm, 12mm, 15mm	IIa
Sterile Skin Graft Blades	Simplex, Duplex	IIa
Sterile Blood Lancet	Standard	IIa
Sterile Myringotomy	Lance and Spear	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Paramount Surgimed Ltd.	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.

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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