



# PARAMOUNT SURGIMED LIMITED

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CIN. : U74899DL1993PLC055981

Ref. No.: PSL-DOC/V-8/ISSUE-06/Rev-02, Dated-16-09-2020

## DECLARATION OF CONFORMITY

According to annex -II excluding section IV of the MDD 93/42/EEC & by amended directive 2007/47/EC concerning medical devices we:



### PARAMOUNT SURGIMED LIMITED

A-106, RIICO Industrial Area, Bhiwadi -301019, District -Alwar, Rajasthan, India

Declare under our sole responsibility that the product:

Name of Device	Classification		Sterile	Variants/ Model	Lot	Mfg. Date	Exp. Date
	Rule	Class					
<b>Dermal Curette in Stainless Steel (Brand- Paramount)</b>	Rule 6, Annex IX	Ila	Sterile by Gamma Irradiation	2 mm, 3 mm, 4mm, 5mm 7mm	XXXXXX	XXXX/XX	XXXX/XX

Meets the provisions of the MDD 93/42/EEC & by amended directive 2007/47/EC concerning medical devices which apply to them:

The MD is in Class Ila, according to annex-IX of the Medical Device Directive and certified as per article 11.3 (a). We have presented our product as well as our quality management system to the notified body 'DNV<sub>2460</sub>' for assessment as per the requirements of MDD 93/42/EEC as amended by 2007/47/EC.

Following standards were used to prove the products conformity with the essential requirements of the Directive:

**Harmonized** EN ISO 14971: 2012, EN ISO 14155: 2011/ AC 2011, EN 62366:2008, EN ISO 10993 -1 : 2009/AC:2010, EN ISO 10993-4:2009, EN ISO 10993-5 : 2009, EN ISO 10993-12:2012, EN ISO 11607-1:2009, EN ISO 11607-2:2006, EN ISO 13485:2016, EN ISO 11737-1: 2009, EN ISO 11737-2:2009, EN ISO 11140-1 : 2009, EN 1041:2008, EN ISO 15223-1:2016, EN ISO 11137-1:2015, EN ISO 11137-2:2015, EN ISO 11138-2 :2009

**Non- Harmonized-** BS 2982:1992, ISO 2859-1:2003, IS 6263:1972, USP 40, ISO 14644-1 :2015, ISO 14644 - 2 : 2015, ISO 14644-8: 2013, ISO 14644-9 : 2012, ISO 14644-10 : 2013, ISO/TC170/SC N 72, BS 5194(Part 1):1991, FSC 6515, 6520 GG-H- 0080a (DSA-DM), IS-10150 : 1981, BS EN-868-5 : 2009, IP 2002, ISO 14644-7:2004, ISO 14698-1:2003, ISO 14698-2:2003, ISO 10993-10:2010, ISO 6507-1:2018, Signatory established within the EU who has been empowered to enter into commitments on our behalf:

### NOTIFIED BODY:

DNV GL PRESAFE AS,  
Veritasveien 3, N-1363 Høvik, Norway  
E-mail: [info@presafe.com](mailto:info@presafe.com)  
Website: [www.presafe.com](http://www.presafe.com)  
NOTIFIED BODY NO: 2460



MDSS GmbH, Schiffgraben 41,  
D-30175, Hannover, Germany  
Email: [info@mdss.com](mailto:info@mdss.com)

CE Certificate No: 10000400574-PA-NA-IND  
Date of Issue: 15 September 2020  
Valid till: 27 May 2024



### For PARAMOUNT SURGIMED LIMITED

Sign & date of issue: 18.09.2020  
Name: Ajay Dhasmana  
Position: Manager QA  
Employee code: PS020



# EC CERTIFICATE

## Full Quality Assurance System

Certificate No.:  
10000400574-PA-NA-IND

Project No.  
PRJC-213992-2010-PRC-IND

Valid Until:  
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](http://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	Ila
Sterile Stitch cutters in Carbon Steel and Stainless Steel	Stitch Cutters Long, Short, Mini	Ila
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	Ila
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	Ila
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	Ila
Sterile Fine Blades / Chisel Blade / Microsurgery blades	61, 62, 63, 64, 65, 66, 67, 68, 69, 69B, 61V, 62V, 90, 91	Ila
Sterile Ophthalmic Blades	Keratome: P-912301, P-912501, P-912601, P-912801, P-912901, P-913201, P-913501, 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,	Ila

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	<p>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</p>	
Sterile Biopsy Punches	Biopsy Punches: 1mm, 1.5mm, 2mm, 2.5mm, 3mm, 3.5mm, 4mm, 5mm, 6mm, 7mm, 8mm, 10mm, 12mm, 15mm	Ila
Sterile Skin Graft Blades	Simplex, Duplex	Ila
Sterile Blood Lancet	Standard	Ila
Sterile Myringotomy	Lance and Spear	Ila

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