PARAMOUNT SURGIMED LIMITED
A-106 RIICO Industrial Area, Bhiwadi Rajasthan-301019
Tel.: +91-11-46436601, 40
Email: sales@paramountblades.com
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Website: www.paramountsurgimedltd.com
Website: www.paramountsurgimed.com
Website: www.paramountblades.com
CIN. : U74899DL1993PLC055981

Ref. No.: PSL-DOC/V-2A, Issue No. 06, Rev-06, Dated-14-10-2024

According to annex –II excluding section IV of the MDD 93/42/EEC & by amended directive 2007/47/EC &Article 120 of MDR(EU) 2017/745 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					
Disposable Scalpel made of Stainless Steel Order No. 1268 (Brand- PARAMOUNT)	Rule 6, Annex IX	IIa	Sterile by Gamma Irradiation	10	HB0583	2024/11	2029/10
				11	HB0584	2024/11	2029/10
				12	HB0585	2024/11	2029/10
				20	HB0586	2024/11	2029/10
				22	HB0587	2024/11	2029/10
				24	HB0588	2024/11	2029/10

Meets the provisions of the MDD 93/42/EEC & by amended directive 2007/47/EC & Article 120 of MDR (EU) 2017/745concerning medical devices which apply to them:

The MD is in Class IIa, 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$_{2460}$' for assessment as per the requirements of MDD 93/42/EEC as amended by 2007/47/EC.

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

Harmonized EN ISO 14971: 2019, BS EN ISO7153-1:2001/BS 5194-1:1991,EN 27740: 1992 (ISO 7740), EN 62366:2008, EN ISO 10993-1:2009, EN ISO 10993-5:2009, EN ISO 10993-10:2023, EN ISO 10993-12:2021, EN ISO 10993-23:2021, EN ISO 11607-1:2009, EN ISO 11607-2:2006, EN ISO 11137-1:2015/A2:2019, EN ISO 11137-2:2015, EN 868-5:2018, EN556-1:2001/AC:2006, EN ISO11140-1:2009,EN ISO13485:2016/A11:2021, EN ISO 11737-1:2018/A1:2021, EN ISO 11737-2:2020, EN ISO 15223-1:2021

Non- Harmonized- BS 2982:1992,ISO 14644-1:2015, ISO 14644-2:2015, ISO 14644-3:2019, ISO 14644-4:2022, ISO 14644-5:2004, ISO 2859-1:1999/ AMD 2011, ISO 780:2015, ISO 2247:2000, ISO 14698 -1: 2003, ISO 14698 -2: 2003, ISO 20417: 2021, ISO 6507-1:2018, ISO 11737-3:2023

Signatory established within the EU who has been empowered to enter into commitments on our behalf:

NOTIFIED BODY:

DNV Product Assurance AS, Veritasveien1, N-1363 Høvik,
Post Box 161, N-1300, Sandvika, Phone-+47 67578800
Website: www.dnv.com
NOTIFIED BODY NO: 2460

EC REP

MDSS GmbH, Schiffgraben 41,
D-30175 Hannover, Germany
Tel. +49 511 6262 8630, Email: info@mdssar.com

CE Certificate No: 10000400574- PA- NA- IND
Date of Issue:15 September 2020
Valid till: 31 December 2028; extended as per Notified Body Confirmation Letter Reference: C684827
For PARAMOUNT SURGIMED LIMITED

Sign & date of issue: 23-11-2024
Name: Meghana
Position: Manager QA&RA

* The batch no. model no. mfg. date and exp. date will be included during issue of the doc to the customer.

EU Quality Management System Certificate

Certificate no.:
C581092

Initial certification date:
08 September 2025

Valid Until:
07 September 2030

This is to certify that the quality system of

Paramount Surgimed Limited

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

SRN: IN-MF-000021682

For design, production, and final product inspection/testing of:

Sterile Disposable Medical Devices

Has been assessed and found to comply with respect to:

The conformity assessment procedure described in Annex IX, (Chapter I & III) of Regulation (EU) 2017/745 on Medical Devices

Place and date:
Høvik, 08 September 2025

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Mariann Jeremiassen
Management Representative

Jurisdiction

Application of Regulation 2017/745 on medical devices, implemented in Norway by Act 7 May 2020 no. 37 on medical devices and Regulation 9 May 2021 no.1476 on medical devices by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Report No.	Issue Date
0.0	Original Certificate	2820506	08 September 2025

Products covered by this Certificate:

Product Description	Product Name	Class
Surgical Blades	Surgical Blades 9, 10, 10A, 11, 11K, 12, 13, 14, 15, 15B, 15C, 15D, 15S, 16, 17, 18, 19, 20, 21, 22, 22A, 23, 24, 25, 26, 36, 40, 40B, 60, 60B, 11P, 12D, 24D, 34, 36D, 1, 2, 3, 4, 5, 6, 8,10,12,15,1R, 2R, 3R, 1V, 2V, 3V	IIa
Skin Graft Blade	Skin Graft Blade Simplex Duplex	IIa
Fine Blades / Chisel Blade	Fine Blades / Chisel Blade Sizes: 61, 61S, 62, 62S, 63, 64, 65, 65A, 67, 68, 69, 90, 91	IIa
Disposable Scalpel with or without safety features	Disposable Scalpel with or without safety features Disposable scalpel: Sizes: 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, 11P, 12D, 24D, 34, 36D Disposable safety scalpel Sizes: 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, 11P, 12D, 24D, 34, 36D	IIa
Biopsy Punch	Biopsy Punch Size: 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 5.0, 6.0, 7.0, 8.0 mm	IIa
Dermal Curette	Dermal Curette Sizes: 2.0, 3.0, 4.0, 5.0, 7.0 mm	IIa
Stitch Cutter	Stitch Cutter Size: MSC, SSC, LSC, MSC with handle	IIa
Myringotomy Knives	Myringotomy Knives Size: Lance & Spear	IIa

Ophthalmic Knives	Slit-Blades (Keratome) For Phaco Stab Incision: P-912301 2.3 MM Sharp Tip Straight P-912501 2.5 MM Sharp Tip Straight P-912601 2.65 MM Sharp Tip Straight P-912801 2.8 MM Sharp Tip Straight P-912901 3.0 MM Sharp Tip Straight P-913201 3.2 MM Sharp Tip Straight P-913501 3.5 MM Sharp Tip Straight P-915101 5.1 MM Sharp Tip Straight P-912361 2.3 MM Sharp Tip Angled 45° 19G P-912561 2.5 MM Sharp Tip Angled 45° 19G P-912661 2.65 MM Sharp Tip Angled 45° 19G P-912861 2.8 MM Sharp Tip Angled 45° 19G P-912961 3.0 MM Sharp Tip Angled 45° 19 G P-913261 3.2 MM Sharp Tip Angled 45° 19 G P-913561 3.5 MM Sharp Tip Angled 45° 19 G P-915061 5.1 MM Sharp Tip Angled 45° 19 G Double Bevel P-912808 2.8 MM Sharp Tip Straight P-912908 3.0 MM Sharp Tip Straight P-913208 3.2 MM Sharp Tip Straight P-912868 2.8 MM Sharp Tip Angled 45° 19G P-912968 3.0 MM Sharp Tip Angled 45° 19G P-913268 3.2 MM Sharp Tip Angled 45° 19G Slit-Blades (Keratome) For I.O.L. Enlarsins: P-914001 4.0 MM Blunt Tip Straight P-915201 5.2 MM Blunt Tip Straight P-915501 5.5 MM Blunt Tip Straight P-916001 6.0 MM Blunt Tip Straight P-916201 6.2 MM Blunt Tip Straight	IIa

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	P-914061 4.0 MM Blunt Tip Angled 45° 16 G P-915561 5.5 MM Blunt Tip Angled 45° 15 G P-916061 6.0 MM Blunt Tip Angled 45° 15 G P-916261 6.2 MM Blunt Tip Angled 45° 15 G Crescent Blades For Groove Or Pocket Or Tunnel Incision: P-950001 Crescent Sharp Tip Straight P-950002 Crescent Bevel Up Angled 45° 20 G P-950003 Crescent Bevel Down Angled 45°20 G Double Bevel P-950004 Crescent Angled 45° 20 Gauge P-950005 Sharp Tip Straight Lance Tip Blades For Initial Incision: P-931501 15° Degree 24 Gauge P-933001 30° Degree 24 Gauge P-934501 45° Degree 24 Gauge MVR Blades For Water Tight Self Sealing Incision: P-975559 MVR 24 Gauge P-975560 MVR 20 Gauge P-975561 MVR 19 Gauge AC STILETIO BLADES For Blumenthal Side Part Incision P-985560 MVR 20 Gauge Angled 45° P-985561 MVR 19 Gauge Angled 45° Miniature Blades Alternative To General Surgery For Precise Incision: SPOON BLADES for Groove or Pocket or Tunnel Incision P-6821 3.0 MM Angled 60° P·6821E 3.0 MM Extended Neck Angled 60 °	

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.
NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 1, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com
MDR-CE-CT54-V2.0

	Miniature Blades Alternative To General Surgery For Precise Incision SCLERAL BLADES For Limbal and Scleral Incision P-5700 Wide Tip Blade P-5710 Narrow Tip Blade	
Dermal blade	Dermal blade Size: Standard	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Paramount Surgimed Limited	A-106, RIICO Industrial Area, Bhiwadi – 301 019, District Alwar, Rajasthan, India

EU Representative
MDSS GmbH, Schiffgraben 41,D-30175 Hannover, Germany Tel. +49 511 6262 8630, Email: info@mdssar.com

Certificate no.: C581092
Place and date: Høvik, 08 September 2025

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 Notified Body of any intended updating of the quality system and the Notified Body 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. Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.
- For the class III devices and IIb devices falling under Article 52 (4) covered this certificate is dependent on the continued validity of the EU Technical Documentation Assessment Certificate, covering the devices.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window

Specific conditions - Class I devices, Systems and Procedure Packs:

- For class I device being placed on the market in a sterile condition, Class I devices with a measurement function and class I devices being reusable surgical instruments covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 52(7) of the regulation.
- For system and procedure packs being placed on the market in a sterile condition, covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 22(3) of the regulation.
- For Custom Made Class III implantable device the certification only relates to the Quality management system. Technical documentation assessment and issuance of EU Technical Documentation Assessment Certificate does not apply.

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.
NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 1, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com