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

Certificate No.:
10000400574-PA-NA-IND

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

Valid Until:
27-05-2024

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.

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

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

Notified Body Confirmation Letter Reference: C684827

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, DNV Product Assurance AS, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB 2460 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

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

SRN Number: IN-MF-000021682

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

Place and date:
Høvik, 06.06.2024

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

Menaka Singh
Management Representative

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function.
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device name: Dermal Curette Size: 2.0, 3.0, 4.0, 5.0, 7.0 mm Basic UDI-DI: 8903175PSLDC65	IIa	Sterile Curette Dermal (Only name change)	MDD certificate Number: 10000400574-PA-NA-IND Appendix rev -0 NoBo Number: 2460 NoBo Name: DNV Product assurance As.
Device name: Stitch Cutter Size - LSC, SSC, MSC Basic UDI-DI: 8903175PSLSC7J	IIa	Sterile Stitch Cutters in carbon steel and stainless steel Long, Short, Mini (Only name change)	MDD certificate Number: 10000400574-PA-NA-IND Appendix rev -0 NoBo Number: 2460 NoBo Name: DNV Product assurance As.
Device name: 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, 36, 40, 40B, 60, 60B, 11P, 12D, 24D, 34, 36D, 1, 2, 3, 4, 5, 6, 8, 1R, 2R, 3R, 1V, 2V, 3V Basic UDI-DI: 8903175PSLSB7G	IIa	Sterile Surgical blades in carbon steel and stainless steel (Only name change)	MDD certificate Number: 10000400574-PA-NA-IND Appendix rev -0 NoBo Number: 2460 NoBo Name: DNV Product assurance As.

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device name: Disposable Scalpel with or without safety features Variants: Disposable scalpel 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 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 Basic UDI-DI: 8903175PSLDS75	IIa	Sterile Disposable Scalpels in carbon steel and stainless steel Sterile Safety Scalpels in carbon steel and stainless steel (Only name change)	MDD certificate Number: 10000400574-PA-NA-IND Appendix rev -0 NoBo Number: 2460 NoBo Name: DNV Product assurance As.
Device name: Fine Blades / Chisel Blade Size - 61, 62, 63, 64, 65, 67, 68, 69, 90, 91 Basic UDI-DI: 8903175PSLCHB6B	IIa	Sterile Fine Blades / Chisel Blade / Microsurgery blades (Only name change)	MDD certificate Number: 10000400574-PA-NA-IND Appendix rev -0 NoBo Number: 2460 NoBo Name: DNV Product assurance As.
Device name: Ophthalmic Knives Keratome: P-912301, P-912501, P-912601, P-912801, P-912901, P-913201, P-913501, 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-915561, P-916061, P-916261 Crescent: P-950001, P-950002, P-950003, P-950004, P-950005 Lance Tip:	IIa	Sterile Ophthalmic Blades Only name change, Model name change only P912901, P912561, P913561, P912868, P915501, P915561, P950005, P985561, P5710	MDD certificate Number: 10000400574-PA-NA-IND Appendix rev -0 NoBo Number: 2460 NoBo Name: DNV Product assurance As.

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
P-931501, P-933001, P-934501, MVR: P-975559, P-975560, P-975561, P-985560, P-985561 Spoon: P-6821, P-6821E Scleral: P-5700, P-5710 Basic UDI-DI: 8903175PSLOPK9H			
Device name: 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 Basic UDI-DI: 8903175PSLBP6R	IIa	Sterile Biopsy Punches (Only name change)	MDD certificate Number: 10000400574-PA-NA-IND Appendix rev -0 NoBo Number: 2460 NoBo Name: DNV Product assurance As.
Device name: Skin Graft Blade Size - Simplex and Duplex Basic UDI-DI: 8903175PSLSG7S	IIa	Sterile Skin Graft Blades (Only name change)	MDD certificate Number: 10000400574-PA-NA-IND Appendix rev -0 NoBo Number: 2460 NoBo Name: DNV Product assurance As.
Device name: Myringotomy Knives Size - Lance & Spear Basic UDI-DI: 8903175PSLMYKA2	IIa	Sterile Myringotomy (Only name change)	MDD certificate Number: 10000400574-PA-NA-IND Appendix rev -0 NoBo Number: 2460 NoBo Name: DNV Product assurance As.

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
NA	NA	NA	NA

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/06/06	C684827	Initial issue

Lack of fulfilment of conditions

The following may render this letter of confirmation invalid:

- Lack of compliance to the requirements of Regulation (EU) 2023/607.
- Significant changes to design or intended purpose of the devices.
- Changes in the quality system affecting production.
- Periodical audits not held within the timeframe.