DNV

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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a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.

003050

ATTESTED

K B Lal Saxena
Executive Assistant
PHD Chamber of Commerce and Industry
New Delhi (INDIA)

CERTIFIED TRUE COPY

PARAMOUNT SURGIMED LTD.

Place and date:
Høvik, 06.06.2024

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

PHD Chamber of Commerce and Industry
30 AUG 2024
New Delhi-110016

Menaka Singh
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this letter invalid.

भारत सरकार GOVERNMENT OF INDIA

अपोस्टिल / APOSTILLE

(Convention de La Haye du 5 octobre 1961)

Country **REPUBLIC OF INDIA**

This public document

COMMERCIAL DOCUMENT

has been signed by AUTHORISED SIGNATORY

acting in the capacity of AUTHORISED SIGNATORY

bears the seal/stamp of PHD CHAMBER OF COMMERCE AND INDUSTRY, NEW DELHI

Certified

at NEW DELHI, INDIA *the* 02-Sep-2024

by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS

No. DLND0008462424

Seal / Stamp

Signature

is issued to PARAMOUNT SURGIMED LTD

OI 2516694

विदेश मंत्रालय MINISTRY OF EXTERNAL AFFAIRS GOVT. OF INDIA, NEW DELHI मु0568

(राजकुमार सिंह)
(RAJ KUMAR SINGH)
अनुभाग अधिकारी (सत्यापन / ओ.आई.)
Section Officer (Attestation / O.I.)
सी.पी.वी. प्रभाग / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi

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.

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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.

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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	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.
Basic UDI-DI: 8903175PSLBP6R Device name: Skin Graft Blade Size - Simplex and Duplex	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.
Basic UDI-DI: 8903175PSLSG7S Device name: Myringotomy Knives Size - Lance & Spear	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.
Basic UDI-DI: 8903175PSLMYKA2			

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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.

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