

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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a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

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

Menaka Singh
Management Representative

Place and date:
Høvik, 06.06.2024



30 AUG 2024



Lack of fulfilment of conditions of the Confirmation Agreement may render this letter invalid.

NOTIFIED BODY 2460 DNV Product Assurance AS, Veritasveien 1, 1363 Høvik, Norway, Tel +47 67 57 88 00. www.dnv.com



भारत सरकार GOVERNMENT OF INDIA
अपोस्टिल / APOSTILLE
(Convention de La Haye du 5 octobre 1961)

Ministry
accepts no res
contents of the a

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

is issued to

PARAMOUNT SURGIMED LTD

Signature

OI 2516694



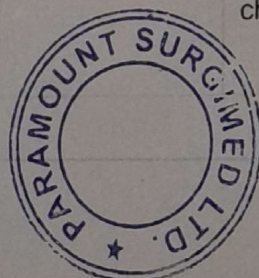
(राजकुमार सिंह)
(RAJ KUMAR SINGH)
अनुभाग अधिकारी (सत्यापन / ओ.आई.)
Section Officer (Attestation / O.I.)
सी.पी.वी. प्रभाग / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi

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: 8903175PSLSC74	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

Ila

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.

Basic UDI-DI: 8903175PSLDS75

Device name: Fine Blades / Chisel
Blade
Size - 61, 62, 63, 64, 65, 67, 68, 69,
90, 91

Ila

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.

Basic UDI-DI: 8903175PSLCHB6B

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:

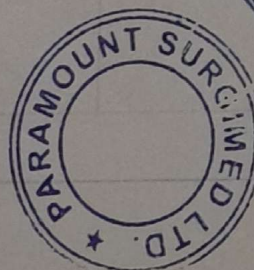
Ila

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	Ila	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. MDD certificate Number: 10000400574-PA-NA-IND Appendix rev -0 NoBo Number: 2460 NoBo Name: DNV Product assurance As. MDD certificate Number: 10000400574-PA-NA-IND Appendix rev -0
Device name: Skin Graft Blade Size - Simplex and Duplex Basic UDI-DI: 8903175PSLSG7S	Ila	Sterile Skin Graft Blades (Only name change)	NoBo Number: 2460 NoBo Name: DNV Product assurance As. MDD certificate Number: 10000400574-PA-NA-IND Appendix rev -0
Device name: Myringotomy Knives Size - Lance & Spear Basic UDI-DI: 8903175PSLMYKA2	Ila	Sterile Myringotomy (Only name change)	NoBo Number: 2460 NoBo Name: DNV Product assurance As.

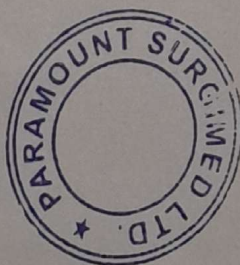
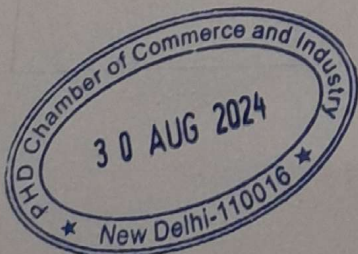


Table 2: Devices covered by this letter and for which the NB is **NOT** responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

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.

