EC CERTIFICATION

EU Quality Management System Certificate

Regulation (EU) 2017/745 for Medical Devices, Annex IX Chapters I & III

We hereby declare that a conformity assessment based on a quality management system and technical documentation has been carried out following the requirements of Regulation (EU) 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

Jai Surgical Limited

B-3, Infocity, Sector 33-34, Gurgaon, Haryana, 122 001, India

Manufacturer SRN: IN-MF-000012813

Authorised Representative: Advena Limited [EN]

Address: Tower Street, BKR4013, Swatar, Malta

Scope:

Surgical instruments

Certificate Number:
28620230984

Revision:
00

Initial Certification Date:
24 November 2025

Certificate Decision Date:
24 November 2025

Certificate Issue Date:
24 November 2025

Certificate Expiry Date:
08 June 2030

Mikael Hagelin
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone.

The certificate remains the property of Intertek, to whom it must be returned upon request.

PRODUCT LIST FOR CERTIFICATE

See attached product list

EXAMINATION AND TESTS PERFORMED

Last Audit report reference	**MDR Stage 1 ACTY-2025-317934**
	MDR Stage 2 ACTY-2025-317938
Last TD assessment reference	**TD00513-001 Biopsy Punches**

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

Reduced duration to align to existing EN ISO certificates expiry date 8 June 2030

Certificate Number:
28620230984

Revision:
00

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08 June 2030

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620230984	2025-11-24	Initial certificate

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PRODUCT LIST FOR CERTIFICATE

Issued to: Jai Surgicals Limited

Certificate number: 28620230984

Certificate valid from: 2025-11-24

Product list issue date:
24 November 2025

Product	Classification and EMDN	Intended use[1]	Date Added
Surgical instruments			
Basic UDI-DI: 8902828BPWM			
Biopsy Punch -Non Sterile, 0.50 to 12 mm - Biopsy Punches 0.50 to 12 mm	Class IIa A01020302		2025-11-24
Biopsy Punches-Sterile, 0.50 to 12 mm - Biopsy Punches 0.50 to 12 mm	Class IIa A01020302		2025-11-24
Basic UDI-DI: 8902828DCVZ			
Dermal Curette-Non Sterile, 2 - Dermal Curette 2	Class IIa A01020303		2025-11-24
Dermal Curette-Non Sterile, 3 - Dermal Curette 3	Class IIa A01020303		2025-11-24
Dermal Curette-Non Sterile, 4 - Dermal Curette 4	Class IIa A01020303		2025-11-24
Dermal Curette-Non Sterile, 5 - Dermal Curette 5	Class IIa A01020303		2025-11-24
Dermal Curette-Non Sterile, 7 - Dermal Curette 7	Class IIa A01020303		2025-11-24
Dermal Curette-Sterile, 2 - Dermal Curette 2	Class IIa A01020303		2025-11-24

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
Dermal Curette-Sterile, 3 - Dermal Curette 3	Class IIa A01020303		2025-11-24
Dermal Curette-Sterile, 4 - Dermal Curette 4	Class IIa A01020303		2025-11-24
Dermal Curette-Sterile, 5 - Dermal Curette 5	Class IIa A01020303		2025-11-24
Dermal Curette-Sterile, 7 - Dermal Curette 7	Class IIa A01020303		2025-11-24
Basic UDI-DI: 8902828DSWZ			
Dental Scalpel -Non sterile - CDM, 15 - Disposable Scalpels 15	Class IIa V010102		2025-11-24
Dental Scalpel -Non sterile- DM, 10-60 - Disposable Scalpels 10-60	Class IIa V010102		2025-11-24
Dental Scalpel -Non sterile- DS, 10-36 - Disposable Scalpels 10-36	Class IIa V010102		2025-11-24
Dental Scalpel -Non sterile -P, 11 - Disposable Scalpels 11	Class IIa V010102		2025-11-24
Dental Scalpel -Non sterile -PA, 11 - Disposable Scalpels 11	Class IIa V010102		2025-11-24
Dental Scalpel -Non sterile -SF, 10-36 - Disposable Scalpels 10-36	Class IIa V010102		2025-11-24
Dental Scalpel -Non sterile, 4-70 - Disposable Scalpels 4-70	Class IIa V010102		2025-11-24
Dental Scalpel -Non sterile-A, 10-25 - Disposable Scalpels 10-25	Class IIa V010102		2025-11-24

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
Dental Scalpel -Non sterile-B, 10-15 - Disposable Scalpels 10-15	Class IIa V010102		2025-11-24
Dental Scalpel -Non sterile-C, 15 - Disposable Scalpels 15	Class IIa V010102		2025-11-24
Dental Scalpel -Non sterile-K, 11 - Disposable Scalpels 11	Class IIa V010102		2025-11-24
Dental Scalpel -Non sterile-OP, 10-60 - Disposable Scalpels 10-60	Class IIa V010102		2025-11-24
Dental Scalpel -Non sterile-R, 10 - Disposable Scalpels 10	Class IIa V010102		2025-11-24
Dental Scalpel -Non sterile-S, 10-15 - Disposable Scalpels 10-15	Class IIa V010102		2025-11-24
Dental Scalpel -Non sterile-T, 15 - Disposable Scalpels 15	Class IIa V010102		2025-11-24
Dental Scalpel- Sterile - CDM, 15 - Disposable Scalpels 15	Class IIa V010102		2025-11-24
Dental Scalpel- Sterile- DM, 10-60 - Disposable Scalpels 10-60	Class IIa V010102		2025-11-24
Dental Scalpel- Sterile- DS, 10-36 - Disposable Scalpels 10-36	Class IIa V010102		2025-11-24
Dental Scalpel- Sterile -P, 11 - Disposable Scalpels 11	Class IIa V010102		2025-11-24
Dental Scalpel- Sterile -PA, 11 - Disposable Scalpels 11	Class IIa V010102		2025-11-24
Dental Scalpel- Sterile -SF, 10-36 - Disposable Scalpels 10-36	Class IIa V010102		2025-11-24
Dental Scalpel- Sterile, 4-70 - Disposable Scalpels 4-70	Class IIa V010102		2025-11-24

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Product	Classification and EMDN	Intended use[1]	Date Added
Dental Scalpel- Sterile-A, 10-25 - Disposable Scalpels 10-25	Class IIa V010102		2025-11-24
Dental Scalpel- Sterile-B, 10-15 - Disposable Scalpels 10-15	Class IIa V010102		2025-11-24
Dental Scalpel- Sterile-C, 15 - Disposable Scalpels 15	Class IIa V010102		2025-11-24
Dental Scalpel- Sterile-K, 11 - Disposable Scalpels 11	Class IIa V010102		2025-11-24
Dental Scalpel- Sterile-OP, 10-60 - Disposable Scalpels 10-60	Class IIa V010102		2025-11-24
Dental Scalpel- Sterile-R, 10 - Disposable Scalpels 10	Class IIa V010102		2025-11-24
Dental Scalpel- Sterile-S, 10-15 - Disposable Scalpels 10-15	Class IIa V010102		2025-11-24
Dental Scalpel- Sterile-T, 15 - Disposable Scalpels 15	Class IIa V010102		2025-11-24
Disposable saclpel-Non sterile - CDM, 15 - Disposable Scalpels 15	Class IIa V010102		2025-11-24
Disposable saclpel-Non sterile- DM, 10-60 - Disposable Scalpels 10-60	Class IIa V010102		2025-11-24
Disposable saclpel-Non sterile- DS, 10-36 - Disposable Scalpels 10-36	Class IIa V010102		2025-11-24
Disposable saclpel-Non sterile -P, 11 - Disposable Scalpels 11	Class IIa V010102		2025-11-24
Disposable saclpel-Non sterile - PA, 11 - Disposable Scalpels 11	Class IIa V010102		2025-11-24

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
Disposable saclpel-Non sterile -SF, 10-36 - Disposable Scalpels 10-36	Class IIa V010102		2025-11-24
Disposable saclpel-Non sterile, 4-70 - Disposable Scalpels 4-70	Class IIa V010102		2025-11-24
Disposable saclpel-Non sterile-A, 10-25 - Disposable Scalpels 10-25	Class IIa V010102		2025-11-24
Disposable saclpel-Non sterile-B, 10-15 - Disposable Scalpels 10-15	Class IIa V010102		2025-11-24
Disposable saclpel-Non sterile-C, 15 - Disposable Scalpels 15	Class IIa V010102		2025-11-24
Disposable saclpel-Non sterile-K, 11 - Disposable Scalpels 11	Class IIa V010102		2025-11-24
Disposable saclpel-Non sterile-OP, 10-60 - Disposable Scalpels 10-60	Class IIa V010102		2025-11-24
Disposable saclpel-Non sterile-R, 10 - Disposable Scalpels 10	Class IIa V010102		2025-11-24
Disposable saclpel-Non sterile-S, 10-15 - Disposable Scalpels 10-15	Class IIa V010102		2025-11-24
Disposable saclpel-Non sterile-T, 15 - Disposable Scalpels 15	Class IIa V010102		2025-11-24
Disposable saclpel-sterile - CDM, 15 - Disposable Scalpels 15	Class IIa V010102		2025-11-24

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
Disposable saclpel-sterile- DM, 10-60 - Disposable Scalpels 10-60	Class IIa V010102		2025-11-24
Disposable saclpel-sterile- DS, 10-36 - Disposable Scalpels 10-36	Class IIa V010102		2025-11-24
Disposable saclpel-sterile -P, 11 - Disposable Scalpels 11	Class IIa V010102		2025-11-24
Disposable saclpel-sterile -PA, 11 - Disposable Scalpels 11	Class IIa V010102		2025-11-24
Disposable saclpel-sterile -SF, 10-36 - Disposable Scalpels 10-36	Class IIa V010102		2025-11-24
Disposable saclpel-sterile, 4-70 - Disposable Scalpels 4-70	Class IIa V010102		2025-11-24
Disposable saclpel-sterile-A, 10-25 - Disposable Scalpels 10-25	Class IIa V010102		2025-11-24
Disposable saclpel-sterile-B, 10-15 - Disposable Scalpels 10-15	Class IIa V010102		2025-11-24
Disposable saclpel-sterile-C, 15 - Disposable Scalpels 15	Class IIa V010102		2025-11-24
Disposable saclpel-sterile-K, 11 - Disposable Scalpels 11	Class IIa V010102		2025-11-24
Disposable saclpel-sterile-OP, 10-60 - Disposable Scalpels 10-60	Class IIa V010102		2025-11-24
Disposable saclpel-sterile-R, 10 - Disposable Scalpels 10	Class IIa V010102		2025-11-24
Disposable saclpel-sterile-S, 10-15 - Disposable Scalpels 10-15	Class IIa V010102		2025-11-24

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Product	Classification and EMDN	Intended use[1]	Date Added
Disposable saclpel-sterile-T, 15 - Disposable Scalpels 15	Class IIa V010102		2025-11-24
Mini Scalpel -Non sterile - CDM, 15 - Disposable Scalpels 15	Class IIa V010102		2025-11-24
Mini Scalpel -Non sterile- DM, 10-15 - Disposable Scalpels 10-15	Class IIa V010102		2025-11-24
Mini Scalpel -Non sterile- DS, 10-15 - Disposable Scalpels 10-15	Class IIa V010102		2025-11-24
Mini Scalpel -Non sterile -P, 11 - Disposable Scalpels 11	Class IIa V010102		2025-11-24
Mini Scalpel -Non sterile -PA, 11 - Disposable Scalpels 11	Class IIa V010102		2025-11-24
Mini Scalpel -Non sterile -SF, 10-15 - Disposable Scalpels 10-15	Class IIa V010102		2025-11-24
Mini Scalpel -Non sterile, 10-15 - Disposable Scalpels 10-15	Class IIa V010102		2025-11-24
Mini Scalpel -Non sterile-A, 10-15 - Disposable Scalpels 10-15	Class IIa V010102		2025-11-24
Mini Scalpel -Non sterile-B, 10-15 - Disposable Scalpels 10-15	Class IIa V010102		2025-11-24
Mini Scalpel -Non sterile-C, 15 - Disposable Scalpels 15	Class IIa V010102		2025-11-24
Mini Scalpel -Non sterile-K, 11 - Disposable Scalpels 11	Class IIa V010102		2025-11-24
Mini Scalpel -Non sterile-OP, 10-15 - Disposable Scalpels 10-15	Class IIa V010102		2025-11-24

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
Mini Scalpel -Non sterile-R, 10 - Disposable Scalpels 10	Class IIa V010102		2025-11-24
Mini Scalpel -Non sterile-S, 10-15 - Disposable Scalpels 10-15	Class IIa V010102		2025-11-24
Mini Scalpel -Non sterile-T, 15 - Disposable Scalpels 15	Class IIa V010102		2025-11-24
Mini scalpel sterile - CDM, 15 - Disposable Scalpels 15	Class IIa V010102		2025-11-24
Mini scalpel sterile- DM, 10-60 - Disposable Scalpels 10-60	Class IIa V010102		2025-11-24
Mini scalpel sterile- DS, 10-36 - Disposable Scalpels 10-36	Class IIa V010102		2025-11-24
Mini scalpel sterile -P, 11 - Disposable Scalpels 11	Class IIa V010102		2025-11-24
Mini scalpel sterile -PA, 11 - Disposable Scalpels 11	Class IIa V010102		2025-11-24
Mini scalpel sterile -SF, 10-36 - Disposable Scalpels 10-36	Class IIa V010102		2025-11-24
Mini scalpel sterile, 10-15 - Disposable Scalpels 10-15	Class IIa V010102		2025-11-24
Mini scalpel sterile-A, 10-15 - Disposable Scalpels 10-15	Class IIa V010102		2025-11-24
Mini scalpel sterile-B, 10-15 - Disposable Scalpels 10-15	Class IIa V010102		2025-11-24
Mini scalpel sterile-C, 15 - Disposable Scalpels 15	Class IIa V010102		2025-11-24
Mini scalpel sterile-K, 11 - Disposable Scalpels 11	Class IIa V010102		2025-11-24

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Product	Classification and EMDN	Intended use[1]	Date Added
Mini scalpel sterile-OP, 10-60 - Disposable Scalpels 10-60	Class IIa V010102		2025-11-24
Mini scalpel sterile-R, 10 - Disposable Scalpels 10	Class IIa V010102		2025-11-24
Mini scalpel sterile-S, 10-15 - Disposable Scalpels 10-15	Class IIa V010102		2025-11-24
Mini scalpel sterile-T, 15 - Disposable Scalpels 15	Class IIa V010102		2025-11-24
Protective Shield Safety with Steadfast Disposal Lock-Non Sterile - CDM, 15 - Disposable Scalpels 15	Class IIa V010101		2025-11-24
Protective Shield Safety with Steadfast Disposal Lock-Non Sterile- DM, 10-60 - Disposable Scalpels 10-60	Class IIa V010101		2025-11-24
Protective Shield Safety with Steadfast Disposal Lock-Non Sterile- DS, 10-36 - Disposable Scalpels 10-36	Class IIa V010101		2025-11-24
Protective Shield Safety with Steadfast Disposal Lock-Non Sterile -P, 11 - Disposable Scalpels 11	Class IIa V010101		2025-11-24
Protective Shield Safety with Steadfast Disposal Lock-Non Sterile -PA, 11 - Disposable Scalpels 11	Class IIa V010101		2025-11-24
Protective Shield Safety with Steadfast Disposal Lock-Non Sterile -SF, 10-36 - Disposable Scalpels 10-36	Class IIa V010101		2025-11-24

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
Protective Shield Safety with Steadfast Disposal Lock-Non Sterile, 4-60 - Disposable Scalpels 4-60	Class IIa V010101		2025-11-24
Protective Shield Safety with Steadfast Disposal Lock-Non Sterile-A, 10-25 - Disposable Scalpels 10-25	Class IIa V010101		2025-11-24
Protective Shield Safety with Steadfast Disposal Lock-Non Sterile-B, 10-15 - Disposable Scalpels 10-15	Class IIa V010101		2025-11-24
Protective Shield Safety with Steadfast Disposal Lock-Non Sterile-C, 15 - Disposable Scalpels 15	Class IIa V010101		2025-11-24
Protective Shield Safety with Steadfast Disposal Lock-Non Sterile-K, 11 - Disposable Scalpels 11	Class IIa V010101		2025-11-24
Protective Shield Safety with Steadfast Disposal Lock-Non Sterile-OP, 10-60 - Disposable Scalpels 10-60	Class IIa V010101		2025-11-24
Protective Shield Safety with Steadfast Disposal Lock-Non Sterile-R, 10 - Disposable Scalpels 10	Class IIa V010101		2025-11-24
Protective Shield Safety with Steadfast Disposal Lock-Non Sterile-S, 10-15 - Disposable Scalpels 10-15	Class IIa V010101		2025-11-24
Protective Shield Safety with Steadfast Disposal Lock-Non Sterile-T, 15 - Disposable Scalpels 15	Class IIa V010101		2025-11-24

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Product	Classification and EMDN	Intended use[1]	Date Added
Protective Shield Safety with Steadfast Disposal Lock-Sterile - CDM, 15 - Disposable Scalpels 15	Class IIa V010101		2025-11-24
Protective Shield Safety with Steadfast Disposal Lock-Sterile- DM, 10-60 - Disposable Scalpels 10-60	Class IIa V010101		2025-11-24
Protective Shield Safety with Steadfast Disposal Lock-Sterile- DS, 10-36 - Disposable Scalpels 10-36	Class IIa V010101		2025-11-24
Protective Shield Safety with Steadfast Disposal Lock-Sterile -P, 11 - Disposable Scalpels 11	Class IIa V010101		2025-11-24
Protective Shield Safety with Steadfast Disposal Lock-Sterile - PA, 11 - Disposable Scalpels 11	Class IIa V010101		2025-11-24
Protective Shield Safety with Steadfast Disposal Lock-Sterile -SF, 10-36 - Disposable Scalpels 10-36	Class IIa V010101		2025-11-24
Protective Shield Safety with Steadfast Disposal Lock-Sterile, 4-60 - Disposable Scalpels 4-60	Class IIa V010101		2025-11-24
Protective Shield Safety with Steadfast Disposal Lock-Sterile-A, 10-25 - Disposable Scalpels 10-25	Class IIa V010101		2025-11-24
Protective Shield Safety with Steadfast Disposal Lock-Sterile-B, 10-15 - Disposable Scalpels 10-15	Class IIa V010101		2025-11-24

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
Protective Shield Safety with Steadfast Disposal Lock-Sterile-C, 15 - Disposable Scalpels 15	Class IIa V010101		2025-11-24
Protective Shield Safety with Steadfast Disposal Lock-Sterile-K, 11 - Disposable Scalpels 11	Class IIa V010101		2025-11-24
Protective Shield Safety with Steadfast Disposal Lock-Sterile-OP, 10-60 - Disposable Scalpels 10-60	Class IIa V010101		2025-11-24
Protective Shield Safety with Steadfast Disposal Lock-Sterile-R, 10 - Disposable Scalpels 10	Class IIa V010101		2025-11-24
Protective Shield Safety with Steadfast Disposal Lock-Sterile-S, 10-15 - Disposable Scalpels 10-15	Class IIa V010101		2025-11-24
Protective Shield Safety with Steadfast Disposal Lock-Sterile-T, 15 - Disposable Scalpels 15	Class IIa V010101		2025-11-24
Retractable Safety with Steadfast Disposal Lock- Non sterile - CDM, 15 - Disposable Scalpels 15	Class IIa V010101		2025-11-24
Retractable Safety with Steadfast Disposal Lock- Non sterile- DM, 10-60 - Disposable Scalpels 10-60	Class IIa V010101		2025-11-24
Retractable Safety with Steadfast Disposal Lock- Non sterile- DS, 10-36 - Disposable Scalpels 10-36	Class IIa V010101		2025-11-24

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
Retractable Safety with Steadfast Disposal Lock- Non sterile -P, 11 - Disposable Scalpels 11	Class IIa V010101		2025-11-24
Retractable Safety with Steadfast Disposal Lock- Non sterile -PA, 11 - Disposable Scalpels 11	Class IIa V010101		2025-11-24
Retractable Safety with Steadfast Disposal Lock- Non sterile -SF, 10-36 - Disposable Scalpels 10-36	Class IIa V010101		2025-11-24
Retractable Safety with Steadfast Disposal Lock- Non sterile, 4-70 - Disposable Scalpels 4-70	Class IIa V010101		2025-11-24
Retractable Safety with Steadfast Disposal Lock- Non sterile-A, 10-25 - Disposable Scalpels 10-25	Class IIa V010101		2025-11-24
Retractable Safety with Steadfast Disposal Lock- Non sterile-B, 10-15 - Disposable Scalpels 10-15	Class IIa V010101		2025-11-24
Retractable Safety with Steadfast Disposal Lock- Non sterile-C, 15 - Disposable Scalpels 15	Class IIa V010101		2025-11-24
Retractable Safety with Steadfast Disposal Lock- Non sterile-K, 11 - Disposable Scalpels 11	Class IIa V010101		2025-11-24
Retractable Safety with Steadfast Disposal Lock- Non sterile-OP, 10-60 - Disposable Scalpels 10-60	Class IIa V010101		2025-11-24
Retractable Safety with Steadfast Disposal Lock- Non sterile-R, 10 - Disposable Scalpels 10	Class IIa V010101		2025-11-24

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
Retractable Safety with Steadfast Disposal Lock- Non sterile-S, 10-15 - Disposable Scalpels 10-15	Class IIa V010101		2025-11-24
Retractable Safety with Steadfast Disposal Lock- Non sterile-T, 15 - Disposable Scalpels 15	Class IIa V010101		2025-11-24
Retractable Safety with Steadfast Disposal Lock- sterile - CDM, 15 - Disposable Scalpels 15	Class IIa V010101		2025-11-24
Retractable Safety with Steadfast Disposal Lock- sterile- DM, 10-60 - Disposable Scalpels 10-60	Class IIa V010101		2025-11-24
Retractable Safety with Steadfast Disposal Lock- sterile- DS, 10-36 - Disposable Scalpels 10-36	Class IIa V010101		2025-11-24
Retractable Safety with Steadfast Disposal Lock- sterile -P, 11 - Disposable Scalpels 11	Class IIa V010101		2025-11-24
Retractable Safety with Steadfast Disposal Lock- sterile -PA, 11 - Disposable Scalpels 11	Class IIa V010101		2025-11-24
Retractable Safety with Steadfast Disposal Lock- sterile -SF, 10-36 - Disposable Scalpels 10-36	Class IIa V010101		2025-11-24
Retractable Safety with Steadfast Disposal Lock- sterile, 4-70 - Disposable Scalpels 4-70	Class IIa V010101		2025-11-24
Retractable Safety with Steadfast Disposal Lock- sterile-A, 10-25 - Disposable Scalpels 10-25	Class IIa V010101		2025-11-24
Retractable Safety with Steadfast Disposal Lock- sterile-B, 10-15 - Disposable Scalpels 10-15	Class IIa V010101		2025-11-24

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
Retractable Safety with Steadfast Disposal Lock- sterile-C, 15 - Disposable Scalpels 15	Class IIa V010101		2025-11-24
Retractable Safety with Steadfast Disposal Lock- sterile-K, 11 - Disposable Scalpels 11	Class IIa V010101		2025-11-24
Retractable Safety with Steadfast Disposal Lock- sterile-OP, 10-60 - Disposable Scalpels 10-60	Class IIa V010101		2025-11-24
Retractable Safety with Steadfast Disposal Lock- sterile-R, 10 - Disposable Scalpels 10	Class IIa V010101		2025-11-24
Retractable Safety with Steadfast Disposal Lock- sterile-S, 10-15 - Disposable Scalpels 10-15	Class IIa V010101		2025-11-24
Retractable Safety with Steadfast Disposal Lock- sterile-T, 15 - Disposable Scalpels 15	Class IIa V010101		2025-11-24
Thumb Scalpel -Non Sterile - CDM, 15 - Disposable Scalpels 15	Class IIa V010102		2025-11-24
Thumb Scalpel -Non Sterile- DM, 10-60 - Disposable Scalpels 10-60	Class IIa V010102		2025-11-24
Thumb Scalpel -Non Sterile- DS, 10-36 - Disposable Scalpels 10-36	Class IIa V010102		2025-11-24
Thumb Scalpel -Non Sterile -P, 11 - Disposable Scalpels 11	Class IIa V010102		2025-11-24
Thumb Scalpel -Non Sterile -PA, 11 - Disposable Scalpels 11	Class IIa V010102		2025-11-24

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
Thumb Scalpel -Non Sterile -SF, 10-36 - Disposable Scalpels 10-36	Class IIa V010102		2025-11-24
Thumb Scalpel -Non Sterile, 4-60 - Disposable Scalpels 4-60	Class IIa V010102		2025-11-24
Thumb Scalpel -Non Sterile-A, 10-25 - Disposable Scalpels 10-25	Class IIa V010102		2025-11-24
Thumb Scalpel -Non Sterile-B, 10-15 - Disposable Scalpels 10-15	Class IIa V010102		2025-11-24
Thumb Scalpel -Non Sterile-C, 15 - Disposable Scalpels 15	Class IIa V010102		2025-11-24
Thumb Scalpel -Non Sterile-K, 11 - Disposable Scalpels 11	Class IIa V010102		2025-11-24
Thumb Scalpel -Non Sterile-OP, 10-60 - Disposable Scalpels 10-60	Class IIa V010102		2025-11-24
Thumb Scalpel -Non Sterile-R, 10 - Disposable Scalpels 10	Class IIa V010102		2025-11-24
Thumb Scalpel -Non Sterile-S, 10-15 - Disposable Scalpels 10-15	Class IIa V010102		2025-11-24
Thumb Scalpel -Non Sterile-T, 15 - Disposable Scalpels 15	Class IIa V010102		2025-11-24
Thumb scalpel- sterile - CDM, 15 - Disposable Scalpels 15	Class IIa V010102		2025-11-24
Thumb scalpel- sterile- DM, 10-60 - Disposable Scalpels 10-60	Class IIa V010102		2025-11-24
Thumb scalpel- sterile- DS, 10-36 - Disposable Scalpels 10-36	Class IIa V010102		2025-11-24

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
Thumb scalpel- sterile -P, 11 - Disposable Scalpels 11	Class IIa V010102		2025-11-24
Thumb scalpel- sterile -PA, 11 - Disposable Scalpels 11	Class IIa V010102		2025-11-24
Thumb scalpel- sterile -SF, 10-36 - Disposable Scalpels 10-36	Class IIa V010102		2025-11-24
Thumb scalpel- sterile, 4-60 - Disposable Scalpels 4-60	Class IIa V010102		2025-11-24
Thumb scalpel- sterile-A, 10-25 - Disposable Scalpels 10-25	Class IIa V010102		2025-11-24
Thumb scalpel- sterile-B, 10-15 - Disposable Scalpels 10-15	Class IIa V010102		2025-11-24
Thumb scalpel- sterile-C, 15 - Disposable Scalpels 15	Class IIa V010102		2025-11-24
Thumb scalpel- sterile-K, 11 - Disposable Scalpels 11	Class IIa V010102		2025-11-24
Thumb scalpel- sterile-OP, 10-60 - Disposable Scalpels 10-60	Class IIa V010102		2025-11-24
Thumb scalpel- sterile-R, 10 - Disposable Scalpels 10	Class IIa V010102		2025-11-24
Thumb scalpel- sterile-S, 10-15 - Disposable Scalpels 10-15	Class IIa V010102		2025-11-24
Thumb scalpel- sterile-T, 15 - Disposable Scalpels 15	Class IIa V010102		2025-11-24
Basic UDI-DI: 8902828SBXC			
Carbon Steel-Non sterile - BB, BB - Surgical Blades BB	Class IIa V010302		2025-11-24
Carbon Steel-Non sterile - CDM, 15 - Surgical Blades 15	Class IIa V010302		2025-11-24

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Product	Classification and EMDN	Intended use[1]	Date Added
Carbon Steel-Non sterile - DM, 10-60 - Surgical Blades 10-60	Class IIa V010302		2025-11-24
Carbon Steel-Non sterile - DS, 10-36 - Surgical Blades 10-36	Class IIa V010302		2025-11-24
Carbon Steel-Non sterile -P, 11 - Surgical Blades 11	Class IIa V010302		2025-11-24
Carbon Steel-Non sterile -PA, 11 - Surgical Blades 11	Class IIa V010302		2025-11-24
Carbon Steel-Non sterile -SF, 10-36 - Surgical Blades 10-36	Class IIa V010302		2025-11-24
Carbon Steel-Non sterile -A, 10-25 - Surgical Blades 10-25	Class IIa V010302		2025-11-24
Carbon Steel-Non sterile -B, 10-15 - Surgical Blades 10-15	Class IIa V010302		2025-11-24
Carbon Steel-Non sterile -C, 15 - Surgical Blades 15	Class IIa V010302		2025-11-24
Carbon Steel-Non sterile -K, 11 - Surgical Blades 11	Class IIa V010302		2025-11-24
Carbon Steel-Non sterile -OP, 10-60 - Surgical Blades 10-60	Class IIa V010302		2025-11-24
Carbon Steel-Non sterile -R, 10 - Surgical Blades 10	Class IIa V010302		2025-11-24
Carbon Steel-Non sterile -S, 10-15 - Surgical Blades 10-15	Class IIa V010302		2025-11-24
Carbon Steel-Non sterile -T, 15 - Surgical Blades 15	Class IIa V010302		2025-11-24

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Product	Classification and EMDN	Intended use[1]	Date Added
Carbon Steel-Non sterile, 4-70 - Surgical Blades 4-70	Class IIa V010302		2025-11-24
Carbon Steel-Sterile - CDM, 15 - Surgical Blades 15	Class IIa V010302		2025-11-24
Carbon Steel-Sterile- BB, BB - Surgical Blades BB	Class IIa V010302		2025-11-24
Carbon Steel-Sterile- DM, 10-60 - Surgical Blades 10-60	Class IIa V010302		2025-11-24
Carbon Steel-Sterile- DS, 10-36 - Surgical Blades 10-36	Class IIa V010302		2025-11-24
Carbon Steel-Sterile -P, 11 - Surgical Blades 11	Class IIa V010302		2025-11-24
Carbon Steel-Sterile -PA, 11 - Surgical Blades 11	Class IIa V010302		2025-11-24
Carbon Steel-Sterile -SF, 10-36 - Surgical Blades 10-36	Class IIa V010302		2025-11-24
Carbon Steel-Sterile, 4-70 - Surgical Blades 4-70	Class IIa V010302		2025-11-24
Carbon Steel-Sterile-A, 10-25 - Surgical Blades 10-25	Class IIa V010302		2025-11-24
Carbon Steel-Sterile-B, 10-15 - Surgical Blades 10-15	Class IIa V010302		2025-11-24
Carbon Steel-Sterile-C, 15 - Surgical Blades 15	Class IIa V010302		2025-11-24
Carbon Steel-Sterile-K , 11 - Surgical Blades 11	Class IIa V010302		2025-11-24
Carbon Steel-Sterile-OP, 10-60 - Surgical Blades 10-60	Class IIa V010302		2025-11-24

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Product	Classification and EMDN	Intended use[1]	Date Added
Carbon Steel-Sterile-R, 10 - Surgical Blades 10	Class IIa V010302		2025-11-24
Carbon Steel-Sterile-S, 10-15 - Surgical Blades 10-15	Class IIa V010302		2025-11-24
Carbon Steel-Sterile-T, 15 - Surgical Blades 15	Class IIa V010302		2025-11-24
Stainless Steel- Non Sterile - CDM, 15 - Surgical Blades 15	Class IIa V010302		2025-11-24
Stainless Steel- Non Sterile BB, BB - Surgical Blades BB	Class IIa V010302		2025-11-24
Stainless Steel- Non Sterile- DM, 10-60 - Surgical Blades 10-60	Class IIa V010302		2025-11-24
Stainless Steel- Non Sterile- DS, 10-36 - Surgical Blades 10-36	Class IIa V010302		2025-11-24
Stainless Steel- Non Sterile -P, 11 - Surgical Blades 11	Class IIa V010302		2025-11-24
Stainless Steel- Non Sterile -PA, 11 - Surgical Blades 11	Class IIa V010302		2025-11-24
Stainless Steel- Non Sterile -SF, 10-36 - Surgical Blades 10-36	Class IIa V010302		2025-11-24
Stainless Steel- Non Sterile, 4-70 - Surgical Blades 4-70	Class IIa V010302		2025-11-24
Stainless Steel- Non Sterile-A, 10-25 - Surgical Blades 10-25	Class IIa V010302		2025-11-24
Stainless Steel- Non Sterile-B, 10-15 - Surgical Blades 10-15	Class IIa V010302		2025-11-24

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Product	Classification and EMDN	Intended use[1]	Date Added
Stainless Steel- Non Sterile-C, 15 - Surgical Blades 15	Class IIa V010302		2025-11-24
Stainless Steel- Non Sterile-K, 11 - Surgical Blades 11	Class IIa V010302		2025-11-24
Stainless Steel- Non Sterile-OP, 10-60 - Surgical Blades 10-60	Class IIa V010302		2025-11-24
Stainless Steel- Non Sterile-R, 10 - Surgical Blades 10	Class IIa V010302		2025-11-24
Stainless Steel- Non Sterile-S, 10-15 - Surgical Blades 10-15	Class IIa V010302		2025-11-24
Stainless Steel- Non Sterile-T, 15 - Surgical Blades 15	Class IIa V010302		2025-11-24
Stainless Steel-Sterile - CDM, 15 - Surgical Blades 15	Class IIa		2025-11-24
Stainless Steel-Sterile - DM , 10-60 - Surgical Blades 10-60	Class IIa V010302		2025-11-24
Stainless Steel-Sterile - DS, 10-36 - Surgical Blades 10-36	Class IIa V010302		2025-11-24
Stainless Steel-Sterile -P, 11 - Surgical Blades 11	Class IIa		2025-11-24
Stainless Steel-Sterile -PA, 11 - Surgical Blades 11	Class IIa V010302		2025-11-24
Stainless Steel-Sterile -SF, 10-36 - Surgical Blades 10-36	Class IIa V010302		2025-11-24
Stainless Steel-Sterile -A, 10-25 - Surgical Blades 10-25	Class IIa V010302		2025-11-24
Stainless Steel-Sterile -B, 10-15 - Surgical Blades 10-15	Class IIa V010302		2025-11-24

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
Stainless Steel-Sterile -BB, BB - Surgical Blades BB	Class IIa V010302		2025-11-24
Stainless Steel-Sterile -C, 15 - Surgical Blades 15	Class IIa V010302		2025-11-24
Stainless Steel-Sterile -K , 11 - Surgical Blades 11	Class IIa V010302		2025-11-24
Stainless Steel-Sterile -OP, 10-60 - Surgical Blades 10-60	Class IIa V010302		2025-11-24
Stainless Steel-Sterile -R, 10 - Surgical Blades 10	Class IIa V010302		2025-11-24
Stainless Steel-Sterile -S, 10-15 - Surgical Blades 10-15	Class IIa V010302		2025-11-24
Stainless Steel-Sterile -T, 15 - Surgical Blades 15	Class IIa V010302		2025-11-24
Stainless Steel-Sterile, 4-70 - Surgical Blades 4-70	Class IIa V010302		2025-11-24



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