

EC CERTIFICATION

QUALITY MANAGEMENT SYSTEM CERTIFICATE

EU Regulation 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 EU Regulation 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.

Razormed Inc

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

Manufacturer SRN: IN-MF-000012812

Authorised Representative Name

ADVENA LIMITED

Tower Business Centre, 2nd flr., Tower Street, Swatar, BKR 4013 Malta.

Scope:

Surgical instruments
Class I reusable instruments
Class I sterile devicesy

Certificate Number:

28620140517

Initial Certification Date:

27 January 2023

Date of Certification Decision:

27 January 2023

Certificate Issue Date:

27 January 2023

Certificate Expiry Date:

14 July 2027



Brian Mather
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.



PRODUCT LIST FOR CERTIFICATE
See attached Product List

EXAMINATION AND TESTS PERFORMED

Technical Assessment Report Reference	TD00062-01 Razormed Inc. Disposable Scalpels
Audit Report Reference	Stage 1 audit ACTY-2022-540488
	Stage 2 audit ACTY-2022-540489

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

Certificate Number:
28620140517

Initial Certification Date:
27 January 2023

Date of Certification Decision:
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14 July 2027




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CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES

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.




Certificate No: 28620140517
Date: 27 January 2023
Handled by: Caroline Åman
E-mail: IMNB@intertek.com

Razormed Inc
Attn: Ambuj Srivastav
B-3, Infocity, Sector 33-34,
Gurgaon , Haryana, 122 001, India

Purpose Assessment to issue a new certificate according to the Medical Device Regulation 2017/745, Annex IX.
Expiry date on MDR certificate is set to be aligned with client’s audit cycle for ISO 13485:2016 certificate.

Activity	Audit Type	Location	Auditor Name	Audit Date
	Stage 1 ACTY-2022-540488	Gurgaon, Haryana	Parvinder Singh	29 May – 1 June 2022
	Stage 2 ACTY-2022-540489	Gurgaon, Haryana	Parvinder Singh	17-19 Nov 2022

Technical Documentation Report	Assessor Name	Assessment Date
Razormed - Blades&Scalpels - Technical Assessment Report - 2023-01-25	Vincenzo Tilotta	25 January 2023
Razormed - Blades&Scalpels - CEAR - 2023-01-25	Vincenzo Tilotta	25 January 2023
Razormed - Blades&Scalpels - RAls - 2023-01-25	Vincenzo Tilotta	25 January 2023

Scope of assessment Surgical instruments
Class I reusable instruments,
Class I sterile devices

Result 0 non conformities were noted during the audit.

All non-conformities noted during the technical documentation assessment(s) have been closed.

Certificate Valid from 27 January 2023

Conclusions/Decisions Referring to the above, a Certificate of Conformance with the Medical Device Regulation 2017/745, Annex IX will be issued. The Certificate is valid for products specified in the “MDR – Product List”.

Follow-up assessments Follow-up assessments are going to be performed once per year.

Appeals Any appeal against this decision will be processed by an appeals panel as Intertek. The appeal shall be submitted to Intertek Medical Notified Body AB, PO-Box 1103, SE-164 22 Kista, Sweden.

Others Any complaints, from customers and others, and corrective actions concerning your certified quality system shall be documented and retained. Upon request Intertek Medical Notified Body has the right to review this documentation.

Intertek Medical Notified Body AB
Notified Body MDR



Brian Mather
Certification Authority

PRODUCT LIST FOR CERTIFICATE

Issued to: Razormed Inc
Certificate number: 28620140517
Certificate valid from: 2023-01-27

Product List Issue Date:
27 January 2023

Product	Classification and EMDN	Intended use ¹	Date Added
Class I reusable instruments			
<i>Basic UDI-DI: 8903376RHX4</i>			
Reusable handle- Non sterile - Reusable handle . Fitment#4	Class I(r) L010103		2023-01-27
Reusable handle- Non sterile - Reusable handle . Fitment#3	Class I(r) L010103		2023-01-27
Class I sterile devices			
<i>Basic UDI-DI: 8903376SCWV</i>			
Carbon steel -sterile - Standard Stitch Cutter (SSC)	Class I(s) V0199		2023-01-27
Carbon steel -sterile - Stitch Cutter (SC)	Class I(s) V0199		2023-01-27
Carbon steel -sterile - Stitch Cutter Long(SCL)	Class I(s) V0199		2023-01-27
Carbon steel -sterile - Stitch Cutter Medium(SCM)	Class I(s) V0199		2023-01-27
Safety Stitch Cutter on a Disposable Handle with Steadfast Disposal Lock- Sterile - Stitch Cutter Stitch Cutter (SC)	Class I(s) V0199		2023-01-27
Stainless steel -Sterile - Standard Stitch Cutter (SSC)	Class I(s) V0199		2023-01-27
Stainless steel -Sterile - Stitch Cutter (SC)	Class I(s) V0199		2023-01-27
Stainless steel -Sterile - Stitch Cutter Long(SCL)	Class I(s) V0199		2023-01-27
Stainless steel -Sterile - Stitch Cutter Medium(SCM)	Class I(s) V0199		2023-01-27
Stitch cutter blade stainless steel with handle -Sterile - Stitch Cutter Stitch Cutter (SC)	Class I(s) V0199		2023-01-27
Surgical instruments			
<i>Basic UDI-DI: 8903376BPW4</i>			

¹The 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
Biopsy Punch -Non Sterile - Biopsy Punches 0.50 to 12 mm	Class IIa A01020302		2023-01-27
Biopsy Punches-Sterile - Biopsy Punches 0.50 to 12 mm	Class IIa A01020302		2023-01-27
Basic UDI-DI: 8903376DCVG			
Derma Curette-Non Sterile - Dermal Curette 2	Class IIa A01020303		2023-01-27
Derma Curette-Non Sterile - Dermal Curette 3	Class IIa A01020303		2023-01-27
Derma Curette-Non Sterile - Dermal Curette 4	Class IIa A01020303		2023-01-27
Derma Curette-Non Sterile - Dermal Curette 5	Class IIa A01020303		2023-01-27
Derma Curette-Non Sterile - Dermal Curette 7	Class IIa A01020303		2023-01-27
Derma Curette-Sterile - Dermal Curette 3	Class IIa A01020303		2023-01-27
Derma Curette-Sterile - Dermal Curette 5	Class IIa A01020303		2023-01-27
Derma Curette-Sterile - Dermal Curette 7	Class IIa A01020303		2023-01-27
Derma Curette-Sterile - Dermal Curette 2	Class IIa A01020303		2023-01-27
Derma Curette-Sterile - Dermal Curette 4	Class IIa A01020303		2023-01-27
Basic UDI-DI: 8903376DSWG			
Dental Scalpel -Non sterile - Disposable Scalpels 4-60	Class IIa V0101		2023-01-27
Dental Scalpel -Non sterile - CDM - Disposable Scalpels 15	Class IIa V0101		2023-01-27
Dental Scalpel -Non sterile- DM - Disposable Scalpels 10-60	Class IIa V0101		2023-01-27
Dental Scalpel -Non sterile- DS - Disposable Scalpels 10-36	Class IIa V0101		2023-01-27
Dental Scalpel -Non sterile -P - Disposable Scalpels 11	Class IIa V0101		2023-01-27
Dental Scalpel -Non sterile -PA - Disposable Scalpels 11	Class IIa V0101		2023-01-27

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

Certificate number: 28620140517

Product list issue date: 27 January 2023



Product	Classification and EMDN	Intended use ¹	Date Added
Dental Scalpel -Non sterile -SF - Disposable Scalpels 10-36	Class IIa V0101		2023-01-27
Dental Scalpel -Non sterile-A - Disposable Scalpels 10-25	Class IIa V0101		2023-01-27
Dental Scalpel -Non sterile-B - Disposable Scalpels 10-15	Class IIa V0101		2023-01-27
Dental Scalpel -Non sterile-C - Disposable Scalpels 15	Class IIa V0101		2023-01-27
Dental Scalpel -Non sterile-K - Disposable Scalpels 11	Class IIa V0101		2023-01-27
Dental Scalpel -Non sterile-OP - Disposable Scalpels 10-60	Class IIa V0101		2023-01-27
Dental Scalpel -Non sterile-R - Disposable Scalpels 10	Class IIa V0101		2023-01-27
Dental Scalpel -Non sterile-S - Disposable Scalpels 10-15	Class IIa V0101		2023-01-27
Dental Scalpel -Non sterile-T - Disposable Scalpels 15	Class IIa V0101		2023-01-27
Dental Scalpel- Sterile - Disposable Scalpels 4-60	Class IIa V0101		2023-01-27
Dental Scalpel- Sterile - CDM - Disposable Scalpels 15	Class IIa V0101		2023-01-27
Dental Scalpel- Sterile- DM - Disposable Scalpels 10-60	Class IIa V0101		2023-01-27
Dental Scalpel- Sterile- DS - Disposable Scalpels 10-36	Class IIa V0101		2023-01-27
Dental Scalpel- Sterile -P - Disposable Scalpels 11	Class IIa V0101		2023-01-27
Dental Scalpel- Sterile -PA - Disposable Scalpels 11	Class IIa V0101		2023-01-27
Dental Scalpel- Sterile -SF - Disposable Scalpels 10-36	Class IIa V0101		2023-01-27

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Product list issue date: 27 January 2023



Product	Classification and EMDN	Intended use ¹	Date Added
Dental Scalpel- Sterile-A - Disposable Scalpels 10-25	Class IIa V0101		2023-01-27
Dental Scalpel- Sterile-B - Disposable Scalpels 10-15	Class IIa V0101		2023-01-27
Dental Scalpel- Sterile-C - Disposable Scalpels 15	Class IIa V0101		2023-01-27
Dental Scalpel- Sterile-K - Disposable Scalpels 11	Class IIa V0101		2023-01-27
Dental Scalpel- Sterile-OP - Disposable Scalpels 10-60	Class IIa V0101		2023-01-27
Dental Scalpel- Sterile-R - Disposable Scalpels 10	Class IIa V0101		2023-01-27
Dental Scalpel- Sterile-S - Disposable Scalpels 10-15	Class IIa V0101		2023-01-27
Dental Scalpel- Sterile-T - Disposable Scalpels 15	Class IIa V0101		2023-01-27
Disposable saclpel-Non sterile - Disposable Scalpels 4-60	Class IIa V0101		2023-01-27
Disposable saclpel-Non sterile - CDM - Disposable Scalpels 15	Class IIa V0101		2023-01-27
Disposable saclpel-Non sterile- DM - Disposable Scalpels 10-60	Class IIa V0101		2023-01-27
Disposable saclpel-Non sterile- DS - Disposable Scalpels 10-36	Class IIa V0101		2023-01-27
Disposable saclpel-Non sterile -P - Disposable Scalpels 11	Class IIa V0101		2023-01-27
Disposable saclpel-Non sterile -PA - Disposable Scalpels 11	Class IIa V0101		2023-01-27
Disposable saclpel-Non sterile -SF - Disposable Scalpels 10-36	Class IIa V0101		2023-01-27
Disposable saclpel-Non sterile-A - Disposable Scalpels 10-25	Class IIa V0101		2023-01-27

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Product	Classification and EMDN	Intended use ¹	Date Added
Disposable saclpel-Non sterile-B - Disposable Scalpels 10-15	Class IIa V0101		2023-01-27
Disposable saclpel-Non sterile-C - Disposable Scalpels 15	Class IIa V0101		2023-01-27
Disposable saclpel-Non sterile-K - Disposable Scalpels 11	Class IIa V0101		2023-01-27
Disposable saclpel-Non sterile-OP - Disposable Scalpels 10-60	Class IIa V0101		2023-01-27
Disposable saclpel-Non sterile-R - Disposable Scalpels 10	Class IIa V0101		2023-01-27
Disposable saclpel-Non sterile-S - Disposable Scalpels 10-15	Class IIa V0101		2023-01-27
Disposable saclpel-Non sterile-T - Disposable Scalpels 15	Class IIa V0101		2023-01-27
Disposable saclpel-sterile - Disposable Scalpels 4-60	Class IIa V0101		2023-01-27
Disposable saclpel-sterile - CDM - Disposable Scalpels 15	Class IIa V0101		2023-01-27
Disposable saclpel-sterile- DM - Disposable Scalpels 10-60	Class IIa V0101		2023-01-27
Disposable saclpel-sterile- DS - Disposable Scalpels 10-36	Class IIa V0101		2023-01-27
Disposable saclpel-sterile -P - Disposable Scalpels 11	Class IIa V0101		2023-01-27
Disposable saclpel-sterile -PA - Disposable Scalpels 11	Class IIa V0101		2023-01-27
Disposable saclpel-sterile -SF - Disposable Scalpels 10-36	Class IIa V0101		2023-01-27
Disposable saclpel-sterile-A - Disposable Scalpels 10-25	Class IIa V0101		2023-01-27
Disposable saclpel-sterile-B - Disposable Scalpels 10-15	Class IIa V0101		2023-01-27

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Product	Classification and EMDN	Intended use ¹	Date Added
Disposable scalpel-sterile-C - Disposable Scalpels 15	Class IIa V0101		2023-01-27
Disposable scalpel-sterile-K - Disposable Scalpels 11	Class IIa V0101		2023-01-27
Disposable scalpel-sterile-OP - Disposable Scalpels 10-60	Class IIa V0101		2023-01-27
Disposable scalpel-sterile-R - Disposable Scalpels 10	Class IIa V0101		2023-01-27
Disposable scalpel-sterile-S - Disposable Scalpels 10-15	Class IIa V0101		2023-01-27
Disposable scalpel-sterile-T - Disposable Scalpels 15	Class IIa V0101		2023-01-27
Mini Scalpel -Non sterile - Disposable Scalpels 4-60	Class IIa V0101		2023-01-27
Mini Scalpel -Non sterile - CDM - Disposable Scalpels 15	Class IIa V0101		2023-01-27
Mini Scalpel -Non sterile- DM - Disposable Scalpels 10-60	Class IIa V0101		2023-01-27
Mini Scalpel -Non sterile- DS - Disposable Scalpels 10-36	Class IIa V0101		2023-01-27
Mini Scalpel -Non sterile -P - Disposable Scalpels 11	Class IIa V0101		2023-01-27
Mini Scalpel -Non sterile -PA - Disposable Scalpels 11	Class IIa V0101		2023-01-27
Mini Scalpel -Non sterile -SF - Disposable Scalpels 10-36	Class IIa V0101		2023-01-27
Mini Scalpel -Non sterile-A - Disposable Scalpels 10-25	Class IIa V0101		2023-01-27
Mini Scalpel -Non sterile-B - Disposable Scalpels 10-15	Class IIa V0101		2023-01-27
Mini Scalpel -Non sterile-C - Disposable Scalpels 15	Class IIa V0101		2023-01-27

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Product list issue date: 27 January 2023



Product	Classification and EMDN	Intended use ¹	Date Added
Mini scalpel sterile-OP - Disposable Scalpels 10-60	Class IIa V0101		2023-01-27
Mini scalpel sterile-R - Disposable Scalpels 10	Class IIa V0101		2023-01-27
Mini scalpel sterile-S - Disposable Scalpels 10-15	Class IIa V0101		2023-01-27
Mini scalpel sterile-T - Disposable Scalpels 15	Class IIa V0101		2023-01-27
Protective Shield Safety with Steadfast Disposal Lock-Non Sterile - Disposable Scalpels 4-60	Class IIa V010101		2023-01-27
Protective Shield Safety with Steadfast Disposal Lock-Non Sterile - CDM - Disposable Scalpels 15	Class IIa V010101		2023-01-27
Protective Shield Safety with Steadfast Disposal Lock-Non Sterile- DM - Disposable Scalpels 10-60	Class IIa V010101		2023-01-27
Protective Shield Safety with Steadfast Disposal Lock-Non Sterile- DS - Disposable Scalpels 10-36	Class IIa V010101		2023-01-27
Protective Shield Safety with Steadfast Disposal Lock-Non Sterile -P - Disposable Scalpels 11	Class IIa V010101		2023-01-27
Protective Shield Safety with Steadfast Disposal Lock-Non Sterile -PA - Disposable Scalpels 11	Class IIa V010101		2023-01-27
Protective Shield Safety with Steadfast Disposal Lock-Non Sterile -SF - Disposable Scalpels 10-36	Class IIa V010101		2023-01-27
Protective Shield Safety with Steadfast Disposal Lock-Non Sterile-A - Disposable Scalpels 10-25	Class IIa V010101		2023-01-27
Protective Shield Safety with Steadfast Disposal Lock-Non Sterile-B - Disposable Scalpels 10-15	Class IIa V010101		2023-01-27

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Product	Classification and EMDN	Intended use ¹	Date Added
Protective Shield Safety with Steadfast Disposal Lock-Non Sterile-C - Disposable Scalpels 15	Class IIa V010101		2023-01-27
Protective Shield Safety with Steadfast Disposal Lock-Non Sterile-K - Disposable Scalpels 11	Class IIa V010101		2023-01-27
Protective Shield Safety with Steadfast Disposal Lock-Non Sterile-OP - Disposable Scalpels 10-60	Class IIa V010101		2023-01-27
Protective Shield Safety with Steadfast Disposal Lock-Non Sterile-R - Disposable Scalpels 10	Class IIa V010101		2023-01-27
Protective Shield Safety with Steadfast Disposal Lock-Non Sterile-S - Disposable Scalpels 10-15	Class IIa V010101		2023-01-27
Protective Shield Safety with Steadfast Disposal Lock-Non Sterile-T - Disposable Scalpels 15	Class IIa V010101		2023-01-27
Protective Shield Safety with Steadfast Disposal Lock-Sterile - Disposable Scalpels 4-60	Class IIa V010101		2023-01-27
Protective Shield Safety with Steadfast Disposal Lock-Sterile - CDM - Disposable Scalpels 15	Class IIa V010101		2023-01-27
Protective Shield Safety with Steadfast Disposal Lock-Sterile- DM - Disposable Scalpels 10-60	Class IIa V010101		2023-01-27
Protective Shield Safety with Steadfast Disposal Lock-Sterile- DS - Disposable Scalpels 10-36	Class IIa V010101		2023-01-27
Protective Shield Safety with Steadfast Disposal Lock-Sterile -P - Disposable Scalpels 11	Class IIa V010101		2023-01-27
Protective Shield Safety with Steadfast Disposal Lock-Sterile -PA - Disposable Scalpels 11	Class IIa V010101		2023-01-27

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Product	Classification and EMDN	Intended use ¹	Date Added
Protective Shield Safety with Steadfast Disposal Lock-Sterile -SF - Disposable Scalpels 10-36	Class IIa V010101		2023-01-27
Protective Shield Safety with Steadfast Disposal Lock-Sterile-A - Disposable Scalpels 10-25	Class IIa V010101		2023-01-27
Protective Shield Safety with Steadfast Disposal Lock-Sterile-B - Disposable Scalpels 10-15	Class IIa V010101		2023-01-27
Protective Shield Safety with Steadfast Disposal Lock-Sterile-C - Disposable Scalpels 15	Class IIa V010101		2023-01-27
Protective Shield Safety with Steadfast Disposal Lock-Sterile-K - Disposable Scalpels 11	Class IIa V010101		2023-01-27
Protective Shield Safety with Steadfast Disposal Lock-Sterile-OP - Disposable Scalpels 10-60	Class IIa V010101		2023-01-27
Protective Shield Safety with Steadfast Disposal Lock-Sterile-R - Disposable Scalpels 10	Class IIa V010101		2023-01-27
Protective Shield Safety with Steadfast Disposal Lock-Sterile-S - Disposable Scalpels 10-15	Class IIa V010101		2023-01-27
Protective Shield Safety with Steadfast Disposal Lock-Sterile-T - Disposable Scalpels 15	Class IIa V010101		2023-01-27
Retractable Safety with Steadfast Disposal Lock- Non sterile - Disposable Scalpels 4-60	Class IIa V010101		2023-01-27
Retractable Safety with Steadfast Disposal Lock- Non sterile - CDM - Disposable Scalpels 15	Class IIa V010101		2023-01-27
Retractable Safety with Steadfast Disposal Lock- Non sterile- DM - Disposable Scalpels 10-60	Class IIa V010101		2023-01-27

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Product	Classification and EMDN	Intended use ¹	Date Added
Retractable Safety with Steadfast Disposal Lock- Non sterile- DS - Disposable Scalpels 10-36	Class IIa V010101		2023-01-27
Retractable Safety with Steadfast Disposal Lock- Non sterile -P - Disposable Scalpels 11	Class IIa V010101		2023-01-27
Retractable Safety with Steadfast Disposal Lock- Non sterile -PA - Disposable Scalpels 11	Class IIa V010101		2023-01-27
Retractable Safety with Steadfast Disposal Lock- Non sterile -SF - Disposable Scalpels 10-36	Class IIa V010101		2023-01-27
Retractable Safety with Steadfast Disposal Lock- Non sterile-A - Disposable Scalpels 10-25	Class IIa V010101		2023-01-27
Retractable Safety with Steadfast Disposal Lock- Non sterile-B - Disposable Scalpels 10-15	Class IIa V010101		2023-01-27
Retractable Safety with Steadfast Disposal Lock- Non sterile-C - Disposable Scalpels 15	Class IIa V010101		2023-01-27
Retractable Safety with Steadfast Disposal Lock- Non sterile-K - Disposable Scalpels 11	Class IIa V010101		2023-01-27
Retractable Safety with Steadfast Disposal Lock- Non sterile-OP - Disposable Scalpels 10-60	Class IIa V010101		2023-01-27
Retractable Safety with Steadfast Disposal Lock- Non sterile-R - Disposable Scalpels 10	Class IIa V010101		2023-01-27
Retractable Safety with Steadfast Disposal Lock- Non sterile-S - Disposable Scalpels 10-15	Class IIa V010101		2023-01-27
Retractable Safety with Steadfast Disposal Lock- Non sterile-T - Disposable Scalpels 15	Class IIa V010101		2023-01-27

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Product	Classification and EMDN	Intended use ¹	Date Added
Retractable Safety with Steadfast Disposal Lock- sterile - Disposable Scalpels 4-60	Class IIa V010101		2023-01-27
Retractable Safety with Steadfast Disposal Lock- sterile - CDM - Disposable Scalpels 15	Class IIa V010101		2023-01-27
Retractable Safety with Steadfast Disposal Lock- sterile- DM - Disposable Scalpels 10-60	Class IIa V010101		2023-01-27
Retractable Safety with Steadfast Disposal Lock- sterile- DS - Disposable Scalpels 10-36	Class IIa V010101		2023-01-27
Retractable Safety with Steadfast Disposal Lock- sterile -P - Disposable Scalpels 11	Class IIa V010101		2023-01-27
Retractable Safety with Steadfast Disposal Lock- sterile -PA - Disposable Scalpels 11	Class IIa V010101		2023-01-27
Retractable Safety with Steadfast Disposal Lock- sterile -SF - Disposable Scalpels 10-36	Class IIa V010101		2023-01-27
Retractable Safety with Steadfast Disposal Lock- sterile-A - Disposable Scalpels 10-25	Class IIa V010101		2023-01-27
Retractable Safety with Steadfast Disposal Lock- sterile-B - Disposable Scalpels 10-15	Class IIa V010101		2023-01-27
Retractable Safety with Steadfast Disposal Lock- sterile-C - Disposable Scalpels 15	Class IIa V010101		2023-01-27
Retractable Safety with Steadfast Disposal Lock- sterile-K - Disposable Scalpels 11	Class IIa V010101		2023-01-27
Retractable Safety with Steadfast Disposal Lock- sterile-OP - Disposable Scalpels 10-60	Class IIa V010101		2023-01-27

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Certificate number: 28620140517

Product list issue date: 27 January 2023



Product	Classification and EMDN	Intended use ¹	Date Added
Retractable Safety with Steadfast Disposal Lock- sterile-R - Disposable Scalpels 10	Class IIa V010101		2023-01-27
Retractable Safety with Steadfast Disposal Lock- sterile-S - Disposable Scalpels 10-15	Class IIa V010101		2023-01-27
Retractable Safety with Steadfast Disposal Lock- sterile-T - Disposable Scalpels 15	Class IIa V010101		2023-01-27
Thumb Scalpel -Non Sterile - Disposable Scalpels 4-60	Class IIa V0101		2023-01-27
Thumb Scalpel -Non Sterile - CDM - Disposable Scalpels 15	Class IIa V0101		2023-01-27
Thumb Scalpel -Non Sterile- DM - Disposable Scalpels 10-60	Class IIa V0101		2023-01-27
Thumb Scalpel -Non Sterile- DS - Disposable Scalpels 10-36	Class IIa V0101		2023-01-27
Thumb Scalpel -Non Sterile -P - Disposable Scalpels 11	Class IIa V0101		2023-01-27
Thumb Scalpel -Non Sterile -PA - Disposable Scalpels 11	Class IIa V0101		2023-01-27
Thumb Scalpel -Non Sterile -SF - Disposable Scalpels 10-36	Class IIa V0101		2023-01-27
Thumb Scalpel -Non Sterile-A - Disposable Scalpels 10-25	Class IIa V0101		2023-01-27
Thumb Scalpel -Non Sterile-B - Disposable Scalpels 10-15	Class IIa V0101		2023-01-27
Thumb Scalpel -Non Sterile-C - Disposable Scalpels 15	Class IIa V0101		2023-01-27
Thumb Scalpel -Non Sterile-K - Disposable Scalpels 11	Class IIa V0101		2023-01-27
Thumb Scalpel -Non Sterile-OP - Disposable Scalpels 10-60	Class IIa V0101		2023-01-27

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Product	Classification and EMDN	Intended use ¹	Date Added
Thumb Scalpel -Non Sterile-R - Disposable Scalpels 10	Class IIa V0101		2023-01-27
Thumb Scalpel -Non Sterile-S - Disposable Scalpels 10-15	Class IIa V0101		2023-01-27
Thumb Scalpel -Non Sterile-T - Disposable Scalpels 15	Class IIa V0101		2023-01-27
Thumb scalpel- sterile - Disposable Scalpels 4-60	Class IIa V0101		2023-01-27
Thumb scalpel- sterile - CDM - Disposable Scalpels 15	Class IIa V0101		2023-01-27
Thumb scalpel- sterile- DM - Disposable Scalpels 10-60	Class IIa V0101		2023-01-27
Thumb scalpel- sterile- DS - Disposable Scalpels 10-36	Class IIa V0101		2023-01-27
Thumb scalpel- sterile -P - Disposable Scalpels 11	Class IIa V0101		2023-01-27
Thumb scalpel- sterile -PA - Disposable Scalpels 11	Class IIa V0101		2023-01-27
Thumb scalpel- sterile -SF - Disposable Scalpels 10-36	Class IIa V0101		2023-01-27
Thumb scalpel- sterile-A - Disposable Scalpels 10-25	Class IIa V0101		2023-01-27
Thumb scalpel- sterile-B - Disposable Scalpels 10-15	Class IIa V0101		2023-01-27
Thumb scalpel- sterile-C - Disposable Scalpels 15	Class IIa V0101		2023-01-27
Thumb scalpel- sterile-K - Disposable Scalpels 11	Class IIa V0101		2023-01-27
Thumb scalpel- sterile-OP - Disposable Scalpels 10-60	Class IIa V0101		2023-01-27
Thumb scalpel- sterile-R - Disposable Scalpels 10	Class IIa V0101		2023-01-27

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Product	Classification and EMDN	Intended use ¹	Date Added
Thumb scalpel- sterile-S - Disposable Scalpels 10-15	Class IIa V0101		2023-01-27
Thumb scalpel- sterile-T - Disposable Scalpels 15	Class IIa V0101		2023-01-27
Basic UDI-DI: 8903376SBWT			
Carbon Steel-Non sterile - Surgical Blades 4-60	Class IIa V0103		2023-01-27
Carbon Steel-Non sterile - CDM - Surgical Blades 15	Class IIa V0103		2023-01-27
Carbon Steel-Non sterile - DM - Surgical Blades 10-60	Class IIa V0103		2023-01-27
Carbon Steel-Non sterile - DS - Surgical Blades 10-36	Class IIa V0103		2023-01-27
Carbon Steel-Non sterile -P - Surgical Blades 11	Class IIa V0103		2023-01-27
Carbon Steel-Non sterile -PA - Surgical Blades 11	Class IIa V0103		2023-01-27
Carbon Steel-Non sterile -SF - Surgical Blades 10-36	Class IIa V0103		2023-01-27
Carbon Steel-Non sterile -A - Surgical Blades 10-25	Class IIa V0103		2023-01-27
Carbon Steel-Non sterile -B - Surgical Blades 10-15	Class IIa V0103		2023-01-27
Carbon Steel-Non sterile -C - Surgical Blades 15	Class IIa V0103		2023-01-27
Carbon Steel-Non sterile -K - Surgical Blades 11	Class IIa V0103		2023-01-27
Carbon Steel-Non sterile -OP - Surgical Blades 10-60	Class IIa V0103		2023-01-27
Carbon Steel-Non sterile -R - Surgical Blades 10	Class IIa V0103		2023-01-27

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Product	Classification and EMDN	Intended use ¹	Date Added
Carbon Steel-Non sterile -S - Surgical Blades 10-15	Class IIa V0103		2023-01-27
Carbon Steel-Non sterile -T - Surgical Blades 15	Class IIa V0103		2023-01-27
Carbon Steel-Sterile - Surgical Blades 4-60	Class IIa V0103		2023-01-27
Carbon Steel-Sterile - CDM - Surgical Blades 15	Class IIa V0103		2023-01-27
Carbon Steel-Sterile- DM - Surgical Blades 10-60	Class IIa V0103		2023-01-27
Carbon Steel-Sterile- DS - Surgical Blades 10-36	Class IIa V0103		2023-01-27
Carbon Steel-Sterile -P - Surgical Blades 11	Class IIa V0103		2023-01-27
Carbon Steel-Sterile -PA - Surgical Blades 11	Class IIa V0103		2023-01-27
Carbon Steel-Sterile -SF - Surgical Blades 10-36	Class IIa V0103		2023-01-27
Carbon Steel-Sterile-A - Surgical Blades 10-25	Class IIa V0103		2023-01-27
Carbon Steel-Sterile-B - Surgical Blades 10-15	Class IIa V0103		2023-01-27
Carbon Steel-Sterile-C - Surgical Blades 15	Class IIa V0103		2023-01-27
Carbon Steel-Sterile-K - Surgical Blades 11	Class IIa V0103		2023-01-27
Carbon Steel-Sterile-OP - Surgical Blades 10-60	Class IIa V0103		2023-01-27
Carbon Steel-Sterile-R - Surgical Blades 10	Class IIa V0103		2023-01-27
Carbon Steel-Sterile-S - Surgical Blades 10-15	Class IIa V0103		2023-01-27
Carbon Steel-Sterile-T - Surgical Blades 15	Class IIa V0103		2023-01-27
Stainless Steel- Non Sterile - Surgical Blades 4-60	Class IIa V0103		2023-01-27
Stainless Steel- Non Sterile - CDM - Surgical Blades 15	Class IIa V0103		2023-01-27

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Product	Classification and EMDN	Intended use ¹	Date Added
Stainless Steel- Non Sterile- DM - Surgical Blades 10-60	Class IIa V0103		2023-01-27
Stainless Steel- Non Sterile- DS - Surgical Blades 10-36	Class IIa V0103		2023-01-27
Stainless Steel- Non Sterile -P - Surgical Blades 11	Class IIa V0103		2023-01-27
Stainless Steel- Non Sterile -PA - Surgical Blades 11	Class IIa V0103		2023-01-27
Stainless Steel- Non Sterile -SF - Surgical Blades 10-36	Class IIa V0103		2023-01-27
Stainless Steel- Non Sterile-A - Surgical Blades 10-25	Class IIa V0103		2023-01-27
Stainless Steel- Non Sterile-B - Surgical Blades 10-15	Class IIa V0103		2023-01-27
Stainless Steel- Non Sterile-C - Surgical Blades 15	Class IIa V0103		2023-01-27
Stainless Steel- Non Sterile-K - Surgical Blades 11	Class IIa V0103		2023-01-27
Stainless Steel- Non Sterile-OP - Surgical Blades 10-60	Class IIa V0103		2023-01-27
Stainless Steel- Non Sterile-R - Surgical Blades 10	Class IIa V0103		2023-01-27
Stainless Steel- Non Sterile-S - Surgical Blades 10-15	Class IIa V0103		2023-01-27
Stainless Steel- Non Sterile-T - Surgical Blades 15	Class IIa V0103		2023-01-27
Stainless steel -Sterile - Surgical Blades 4-60	Class IIa V0103		2023-01-27
Stainless Steel-Sterile - CDM - Surgical Blades 15	Class IIa V0103		2023-01-27
Stainless Steel-Sterile - DM - Surgical Blades 10-60	Class IIa V0103		2023-01-27

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Product	Classification and EMDN	Intended use ¹	Date Added
Stainless Steel-Sterile - DS - Surgical Blades 10-36	Class IIa V0103		2023-01-27
Stainless Steel-Sterile -P - Surgical Blades 11	Class IIa V0103		2023-01-27
Stainless Steel-Sterile -PA - Surgical Blades 11	Class IIa V0103		2023-01-27
Stainless Steel-Sterile -SF - Surgical Blades 10-36	Class IIa V0103		2023-01-27
Stainless Steel-Sterile -A - Surgical Blades 10-25	Class IIa V0103		2023-01-27
Stainless Steel-Sterile -B - Surgical Blades 10-15	Class IIa V0103		2023-01-27
Stainless Steel-Sterile -C - Surgical Blades 15	Class IIa V0103		2023-01-27
Stainless Steel-Sterile -K - Surgical Blades 11	Class IIa V0103		2023-01-27
Stainless Steel-Sterile -OP - Surgical Blades 10-60	Class IIa V0103		2023-01-27
Stainless Steel-Sterile -R - Surgical Blades 10	Class IIa V0103		2023-01-27
Stainless Steel-Sterile -S - Surgical Blades 10-15	Class IIa V0103		2023-01-27
Stainless Steel-Sterile -T - Surgical Blades 15	Class IIa V0103		2023-01-27

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Product	Classification and EMDN	Intended use ¹	Date Added
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Brian Mather

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.

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