

# **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

- 1		
	None	
	None	

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#### **CERTIFICATE HISTORY**

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES

**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 B accordance with the requirements set out in EU R 2017/745 on medical devices, with the identifical







## **MDR – Decision Report**

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	Gurgaon,	Parvinder	29 May – 1
ACTY-2022-540488	Haryana	Singh	June 2022
Stage 2	Gurgaon,	Parvinder	17-19 Nov
ACTY-2022-540489	Haryana	Singh	2022

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



# **MDR – Decision Report**

**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 <sup>1</sup>	Date Added
Class I reusable instruments			
Basic UDI-DI: 8903376RHX4			
Reusable handle- Non sterile -	Class I(r)		2023-01-27
Reusable handle . Fitment#4	L010103		
Reusable handle- Non sterile -	Class I(r)		2023-01-27
Reusable handle . Fitment#3	L010103		
Class I sterile devices			
Basic UDI-DI: 8903376SCWV			
Carbon steel -sterile - Standard Stitch	Class I(s)		2023-01-27
Cutter (SSC)	V0199		
Carbon steel -sterile - Stitch Cutter (SC)	Class I(s)		2023-01-27
	V0199		
Carbon steel -sterile - Stitch Cutter	Class I(s)		2023-01-27
Long(SCL)	V0199		
Carbon steel -sterile - Stitch Cutter	Class I(s)		2023-01-27
Medium(SCM)	V0199		
Safety Stitch Cutter on a Disposable	Class I(s)		2023-01-27
Handle with Steadfast Disposal Lock-	V0199		
Sterile - Stitch Cutter			
Stitch Cutter (SC)			
Stainless steel -Sterile - Standard Stitch	Class I(s)		2023-01-27
Cutter (SSC)	V0199		diamental and the second secon
Stainless steel -Sterile - Stitch Cutter	Class I(s)		2023-01-27
(SC)	V0199		
Stainless steel -Sterile - Stitch Cutter	Class I(s)		2023-01-27
Long(SCL)	V0199		2022.04.27
Stainless steel -Sterile - Stitch Cutter	Class I(s)		2023-01-27
Medium(SCM)	V0199		2022.04.27
Stitch cutter blade stainless steel with handle -Sterile - Stitch Cutter	Class I(s) V0199		2023-01-27
Stitch Cutter (SC)	40122		
Surgical instruments			









Product	Classification and EMDN	Intended use <sup>1</sup>	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			
Dermal Curette-Non Sterile - Dermal Curette 2	Class IIa A01020303		2023-01-27
Dermal Curette-Non Sterile - Dermal Curette 3	Class IIa A01020303		2023-01-27
Dermal Curette-Non Sterile - Dermal Curette 4	Class IIa A01020303		2023-01-27
Dermal Curette-Non Sterile - Dermal Curette 5	Class IIa A01020303		2023-01-27
Dermal Curette-Non Sterile - Dermal Curette 7	Class IIa A01020303		2023-01-27
Dermal Curette-Sterile - Dermal Curette 3	Class IIa A01020303		2023-01-27
Dermal Curette-Sterile - Dermal Curette 5	Class IIa A01020303		2023-01-27
Dermal Curette-Sterile - Dermal Curette 7	Class IIa A01020303		2023-01-27
Dermal Curette-Sterile - Dermal Curette 2	Class IIa A01020303		2023-01-27
Dermal Curette-Sterile - Dermal Curette 4	Class IIa A01020303		2023-01-27
Basic UDI-DI: 8903376DSWG			
Dental Scalpel -Non sterile - Disposable Scalpels 4-60	Class Ila 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

<sup>&</sup>lt;sup>1</sup>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 <sup>1</sup>	Date Added
Dental Scalpel -Non sterile -SF - Disposable Scalpels 10-36	Class Ila 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

<sup>&</sup>lt;sup>1</sup>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 <sup>1</sup>	Date Added
Dental Scalpel- Sterile-A - Disposable Scalpels	Class IIa V0101		2023-01-27
10-25	V0101		
O's Trees	Classilla		2022.01.27
Dental Scalpel- Sterile-B - Disposable	Class IIa		2023-01-27
Scalpels 10-15	V0101		
	Classilla		2022.01.27
Dental Scalpel- Sterile-C - Disposable	Class IIa V0101		2023-01-27
Scalpels 15	V0101		
	Class II.		2022.04.27
Dental Scalpel- Sterile-K - Disposable	Class IIa		2023-01-27
Scalpels	V0101		
11			
Dental Scalpel- Sterile-OP - Disposable	Class IIa		2023-01-27
Scalpels	V0101		
10-60			
Dental Scalpel- Sterile-R - Disposable	Class IIa		2023-01-27
Scalpels	V0101		
10	COLUMN TO THE STATE OF THE STAT		
Dental Scalpel- Sterile-S - Disposable	Class IIa		2023-01-27
Scalpels	V0101		
10-15			
Dental Scalpel- Sterile-T - Disposable	Class IIa		2023-01-27
Scalpels	V0101		
15			
Disposable saclpel-Non sterile -	Class IIa		2023-01-27
Disposable Scalpels	V0101		
4-60			
Disposable sacIpel-Non sterile - CDM -	Class IIa		2023-01-27
Disposable Scalpels	V0101		
15			
Disposable saclpel-Non sterile- DM -	Class IIa		2023-01-27
Disposable Scalpels	V0101		
10-60			
Disposable saclpel-Non sterile- DS -	Class IIa		2023-01-27
Disposable Scalpels	V0101		
10-36			
Disposable saclpel-Non sterile -P -	Class IIa		2023-01-27
Disposable Scalpels	V0101		
11			
Disposable saclpel-Non sterile -PA -	Class IIa		2023-01-27
Disposable Scalpels	V0101		
11			
Disposable sacipel-Non sterile -SF -	Class IIa		2023-01-27
Disposable Scalpels	V0101		
10-36	16.6		
Disposable saclpel-Non sterile-A -	Class IIa		2023-01-27
Disposable Scalpels	V0101		2023-01-27
10-25	40101		

<sup>&</sup>lt;sup>1</sup>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 <sup>1</sup>	Date Added
Disposable saclpel-Non sterile-B - Disposable Scalpels 10-15	Class IIa V0101		2023-01-27
Disposable saclpel-Non sterile-C - Disposable Scalpels	Class IIa V0101		2023-01-27
15 Disposable saclpel-Non sterile-K -	Class IIa		2023-01-27
Disposable Scalpels 11	V0101		
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

<sup>&</sup>lt;sup>1</sup>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 <sup>1</sup>	Date Added
Disposable saclpel-sterile-C -	Class IIa		2023-01-27
Disposable Scalpels	V0101		
15			
Disposable saclpel-sterile-K -	Class IIa		2023-01-27
Disposable Scalpels	V0101		
11			
Disposable saclpel-sterile-OP -	Class IIa		2023-01-27
Disposable Scalpels	V0101		
10-60			
Disposable saclpel-sterile-R -	Class IIa		2023-01-27
Disposable Scalpels	V0101		
10			
Disposable saclpel-sterile-S -	Class IIa		2023-01-27
Disposable Scalpels	V0101		
10-15			
Disposable saclpel-sterile-T -	Class IIa		2023-01-27
Disposable Scalpels	V0101		
15			
Mini Scalpel -Non sterile - Disposable	Class IIa		2023-01-27
Scalpels	V0101		
4-60			
Mini Scalpel -Non sterile - CDM -	Class IIa		2023-01-27
Disposable Scalpels	V0101		
15			
Mini Scalpel -Non sterile- DM -	Class IIa		2023-01-27
Disposable Scalpels	V0101		2020 02 27
10-60			
Mini Scalpel -Non sterile- DS -	Class IIa		2023-01-27
Disposable Scalpels	V0101		2020 01 27
10-36			
Mini Scalpel -Non sterile -P -	Class IIa		2023-01-27
Disposable Scalpels	V0101		2020 02 27
11	~~~~		
Mini Scalpel -Non sterile -PA -	Class IIa		2023-01-27
Disposable Scalpels	V0101		2020 01 27
11			
Mini Scalpel -Non sterile -SF -	Class IIa		2023-01-27
Disposable Scalpels	V0101		2020 01 27
10-36	2777		
Mini Scalpel -Non sterile-A - Disposable	Class IIa		2023-01-27
Scalpels	V0101		2023-01-27
10-25	, , , , ,		
Mini Scalpel -Non sterile-B - Disposable	Class IIa		2023-01-27
Scalpels	V0101		2023-01-27
10-15	40101		
	Class IIa		2022.04.27
Mini Scalpel -Non sterile-C - Disposable Scalpels	Class IIa V0101		2023-01-27
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<sup>&</sup>lt;sup>1</sup>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 <sup>1</sup>	Date Added
Mini scalpel sterile-OP - Disposable Scalpels	Class Ila V0101		2023-01-27
10-60			
Mini scalpel sterile-R - Disposable	Class IIa		2023-01-27
Scalpels	V0101		
10			
Mini scalpel sterile-S - Disposable	Class IIa		2023-01-27
Scalpels	V0101		
10-15			
Mini scalpel sterile-T - Disposable	Class IIa		2023-01-27
Scalpels	V0101		
15			
Protective Shield Safety with Steadfast	Class IIa		2023-01-27
Disposal Lock-Non Sterile - Disposable	V010101		
Scalpels	,010101		
4-60			
Protective Shield Safety with Steadfast	Class IIa		2023-01-27
Disposal Lock-Non Sterile - CDM -	V010101		2023-01-27
Disposable Scalpels	V010101		
15			
	61 11		2022.04.27
Protective Shield Safety with Steadfast	Class IIa		2023-01-27
Disposal Lock-Non Sterile- DM -	V010101		
Disposable Scalpels			
10-60			
Protective Shield Safety with Steadfast	Class IIa		2023-01-27
Disposal Lock-Non Sterile- DS -	V010101		
Disposable Scalpels			
10-36			
Protective Shield Safety with Steadfast	Class IIa		2023-01-27
Disposal Lock-Non Sterile -P -	V010101		
Disposable Scalpels			
11			
Protective Shield Safety with Steadfast	Class IIa		2023-01-27
Disposal Lock-Non Sterile -PA -	V010101		
Disposable Scalpels	A020013		
11			
Protective Shield Safety with Steadfast	Class IIa		2023-01-27
Disposal Lock-Non Sterile -SF -	V010101		2025-01-2/
Disposable Scalpels	1010101		
10-36			
2 4 1	Class II		2022 04 07
Protective Shield Safety with Steadfast	Class IIa		2023-01-27
Disposal Lock-Non Sterile-A -	V010101		
Disposable Scalpels			
10-25			
Protective Shield Safety with Steadfast	Class IIa		2023-01-27
Disposal Lock-Non Sterile-B -	V010101		
Disposable Scalpels			
10-15			







Product	Classification and EMDN	Intended use <sup>1</sup>	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	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 Ila V010101		2023-01-27
Protective Shield Safety with Steadfast Disposal Lock-Sterile -PA - Disposable Scalpels 11	Class Ila V010101		2023-01-27







Product	Classification and EMDN	Intended use <sup>1</sup>	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	Class IIa V010101		2023-01-27
Protective Shield Safety with Steadfast Disposal Lock-Sterile-K - Disposable Scalpels	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	Class IIa V010101		2023-01-27
Protective Shield Safety with Steadfast Disposal Lock-Sterile-S - Disposable Scalpels	Class IIa V010101		2023-01-27
Protective Shield Safety with Steadfast Disposal Lock-Sterile-T - Disposable Scalpels	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 L5	Class Ila V010101		2023-01-27
Retractable Safety with Steadfast Disposal Lock- Non sterile- DM - Disposable Scalpels 10-60	Class Ila V010101		2023-01-27







Product	Classification and EMDN	Intended use <sup>1</sup>	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







Product	Classification and EMDN	Intended use <sup>1</sup>	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







Product	Classification and EMDN	Intended use <sup>1</sup>	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







Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
Thumb Scalpel -Non Sterile-R -	Class IIa		2023-01-27
Disposable Scalpels	V0101		
10			
Thumb Scalpel -Non Sterile-S -	Class IIa		2023-01-27
Disposable Scalpels	V0101		
10-15			
Thumb Scalpel -Non Sterile-T -	Class IIa		2023-01-27
Disposable Scalpels	V0101		
15			
Thumb scalpel- sterile - Disposable	Class IIa		2023-01-27
Scalpels	V0101		
4-60			
Thumb scalpel- sterile - CDM -	Class IIa		2023-01-27
Disposable Scalpels	V0101		
15			
Thumb scalpel- sterile- DM -	Class IIa		2023-01-27
Disposable Scalpels	V0101		
10-60			
Thumb scalpel- sterile- DS - Disposable	Class IIa		2023-01-27
Scalpels	V0101		
10-36			
Thumb scalpel- sterile -P - Disposable	Class IIa		2023-01-27
Scalpels	V0101		
11			
Thumb scalpel- sterile -PA - Disposable	Class IIa		2023-01-27
Scalpels	V0101		
11			
Thumb scalpel- sterile -SF - Disposable	Class IIa		2023-01-27
Scalpels	V0101		
10-36	2.1.21.2		
Thumb scalpel- sterile-A - Disposable	Class IIa		2023-01-27
Scalpels	V0101		
10-25			
Thumb scalpel- sterile-B - Disposable	Class IIa		2023-01-27
Scalpels	V0101		
10-15			
Thumb scalpel- sterile-C - Disposable	Class IIa		2023-01-27
Scalpels	V0101		
15			
Thumb scalpel- sterile-K - Disposable	Class IIa		2023-01-27
Scalpels	V0101		
11			
Thumb scalpel- sterile-OP - Disposable	Class IIa		2023-01-27
Scalpels	V0101		2023 01 27
10-60	7 7 7 7 7		
Thumb scalpel- sterile-R - Disposable	Class IIa		2023-01-27
Scalpels	V0101		2023-01-27
realbeig	A0101		

<sup>&</sup>lt;sup>1</sup>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 <sup>1</sup>	Date Added
Thumb scalpel- sterile-S - Disposable	Class IIa		2023-01-27
Scalpels	V0101		
10-15			
Thumb scalpel- sterile-T - Disposable	Class IIa		2023-01-27
Scalpels	V0101		
15			
Basic UDI-DI: 8903376SBWT			
Carbon Steel-Non sterile - Surgical	Class IIa		2023-01-27
Blades	V0103		
4-60			
Carbon Steel-Non sterile - CDM -	Class IIa		2023-01-27
Surgical Blades	V0103		
15			
Carbon Steel-Non sterile - DM -	Class IIa		2023-01-27
Surgical Blades	V0103		
10-60	115777		
Carbon Steel-Non sterile - DS - Surgical	Class IIa		2023-01-27
Blades	V0103		2023-01-27
10-36	V0103		
Carbon Steel-Non sterile -P - Surgical	Class IIa		2023-01-27
Blades			2023-01-27
11	V0103		
	Class IIa		2022 04 27
Carbon Steel-Non sterile -PA - Surgical	V0103		2023-01-27
Blades	V0103		
11	ALC: N		
Carbon Steel-Non sterile -SF - Surgical	Class IIa		2023-01-27
Blades	V0103		
10-36			
Carbon Steel-Non sterile -A - Surgical	Class IIa		2023-01-27
Blades	V0103		
10-25			
Carbon Steel-Non sterile -B - Surgical	Class IIa		2023-01-27
Blades	V0103		
10-15			
Carbon Steel-Non sterile -C - Surgical	Class IIa		2023-01-27
Blades	V0103		
15			
Carbon Steel-Non sterile -K - Surgical	Class IIa		2023-01-27
Blades	V0103		
11			
Carbon Steel-Non sterile -OP - Surgical	Class IIa		2023-01-27
Blades	V0103		2020 01 27
10-60	, , , , , , , , , , , , , , , , , , , ,		
Carbon Steel-Non sterile -R - Surgical	Class IIa		2023-01-27
Blades	V0103		2023-01-27
Diaues	10102		

<sup>&</sup>lt;sup>1</sup>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 <sup>1</sup>	Date Added
Carbon Steel-Non sterile -S - Surgical	Class IIa		2023-01-27
Blades	V0103		
10-15			
Carbon Steel-Non sterile -T - Surgical	Class IIa		2023-01-27
Blades	V0103		
15			
Carbon Steel-Sterile - Surgical Blades	Class IIa		2023-01-27
4-60	V0103		
Carbon Steel-Sterile - CDM - Surgical	Class IIa		2023-01-27
Blades	V0103		
15			
Carbon Steel-Sterile- DM - Surgical	Class IIa		2023-01-27
Blades	V0103		
10-60			
Carbon Steel-Sterile- DS - Surgical	Class IIa		2023-01-27
Blades	V0103		
10-36			
Carbon Steel-Sterile -P - Surgical Blades	Class IIa		2023-01-27
11	V0103		
Carbon Steel-Sterile -PA - Surgical	Class IIa		2023-01-27
Blades	V0103		
11			
Carbon Steel-Sterile -SF - Surgical	Class IIa		2023-01-27
Blades	V0103		
10-36			
Carbon Steel-Sterile-A - Surgical Blades	Class IIa		2023-01-27
10-25	V0103		
Carbon Steel-Sterile-B - Surgical Blades	Class IIa		2023-01-27
10-15	V0103		
Carbon Steel-Sterile-C - Surgical Blades	Class IIa		2023-01-27
15	V0103		
Carbon Steel-Sterile-K - Surgical Blades	Class IIa		2023-01-27
11	V0103		2025 01 27
Carbon Steel-Sterile-OP - Surgical	Class IIa		2023-01-27
Blades	V0103		2025-01-27
10-60	,0103		
Carbon Steel-Sterile-R - Surgical Blades	Class IIa		2023-01-27
10	V0103		2025-01-2/
	Class IIa		2023-01-27
Carbon Steel-Sterile-S - Surgical Blades 10-15	V0103		2023-01-2/
	-0.00		2022 04 27
Carbon Steel-Sterile-T - Surgical Blades	Class IIa		2023-01-27
15	V0103	=	
Stainless Steel- Non Sterile - Surgical	Class IIa		2023-01-27
Blades	V0103		
4-60			
Stainless Steel- Non Sterile - CDM -	Class IIa		2023-01-27
Surgical Blades	V0103		
15			

<sup>&</sup>lt;sup>1</sup>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 <sup>1</sup>	Date Added
Stainless Steel- Non Sterile- DM -	Class IIa		2023-01-27
Surgical Blades	V0103		
10-60			
Stainless Steel- Non Sterile- DS -	Class IIa		2023-01-27
Surgical Blades	V0103		
10-36			
Stainless Steel- Non Sterile -P - Surgical	Class IIa		2023-01-27
Blades	V0103		
11			
Stainless Steel- Non Sterile -PA -	Class IIa		2023-01-27
Surgical Blades	V0103		
11			
Stainless Steel- Non Sterile -SF -	Class IIa		2023-01-27
Surgical Blades	V0103		
10-36	7.7.7.7.		
Stainless Steel- Non Sterile-A - Surgical	Class IIa		2023-01-27
Blades	V0103		2020 01 27
10-25	10100		
Stainless Steel- Non Sterile-B - Surgical	Class IIa		2023-01-27
Blades	V0103		2023-01-27
10-15	V0103		
Stainless Steel- Non Sterile-C - Surgical	Class IIa		2023-01-27
Blades	V0103		2023-01-27
15	V0103		
Stainless Steel- Non Sterile-K - Surgical	Class IIa		2023-01-27
Blades			2023-01-27
11	V0103		
	61		2022.04.27
Stainless Steel- Non Sterile-OP -	Class IIa		2023-01-27
Surgical Blades	V0103		
10-60			
Stainless Steel- Non Sterile-R - Surgical	Class IIa		2023-01-27
Blades	V0103		
10	F-17-12-2		
Stainless Steel- Non Sterile-S - Surgical	Class IIa		2023-01-27
Blades	V0103		
10-15			
Stainless Steel- Non Sterile-T - Surgical	Class IIa		2023-01-27
Blades	V0103		
15			
Stainless steel -Sterile - Surgical Blades	Class IIa		2023-01-27
4-60	V0103		
Stainless Steel-Sterile - CDM - Surgical	Class IIa		2023-01-27
Blades	V0103		
15			
Stainless Steel-Sterile - DM - Surgical	Class IIa		2023-01-27
Blades	V0103		
10-60			







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







Product Classification and EMDN Intended use<sup>1</sup> Date Added

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.

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



