Declaration of Conformity

Name of Manufacturer	**RAZORMED INC.**
Address of the manufacturer	B-3, Infocity, Sector 33-34, Gurgaon, Haryana 122001, India Contact No: +91 124 433 8888 Fax: +91 124 433 8800 Email ID: info@razormed.com Website: www.razormed.com
Manufacturer SRN	IN-MF-000012812
Name of the Authorized Representative	Advena Limited
Address of the Authorized Representative	Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
Representative SRN	MT-AR-000000234
Notified Body Name	Intertek Medical Notified Body AB
Address of Notified Body	Torshamn sgatan 43, Box 1103, SE-164 22 Kista, Sweden
Contact details of the Notified Body	Phone: +46 8 750 00 00 Fax: +46 8 750 60 30 Email: IMNB@intertek.com
Notified Body Number	2862
Description of Conformity Assessment Procedure	Regulation (EU) 2017/745 Annex IX Chapter I & III
Certificate Number **Class Is and Ir** **Class IIa**	**28620140517** **28620239980**
Validity of the certificate	14 July 2027

RAZORMED INC. hereby under its own and exclusive responsibility declares that the products covered within this declaration conform to the General Safety and Performance Requirements listed in Annex I of EU MDR (Regulation EU 2017/745). Supporting documentation in the form of the Technical File is retained under the premises of the manufacturer. This document contains both product-specific and process (Quality Management System) specific information. Common Spefications are not present.

RAZORMED INC. has its Quality Management System in place in compliance with EN ISO 13485:2016/A11:2021, Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes.

Applicable Harmonised Standards:

EN ISO 13485:2016/A11:2021, EN ISO 11137-1:2015/A2:2019, EN 10088-3:2023, EN ISO 11137-2:2015/A1:2023, EN ISO 13402:2025, EN ISO 10993-11:2018, EN ISO 10993-5:2009, EN 27740:2000/A1:2000, EN ISO 11607-1:2020/A1:2023, EN ISO 11607-2:2020/A1:2023, EN ISO 11737-2:2020, EN ISO 15223-1:2021, EN ISO 11737-1:2018/A1:2021, EN 868-5:2018, EN ISO 14971:2019/A11:2021 , EN ISO 20417:2021, EN 10088-1:2023, EN ISO 7153-1:2016(ISO 7153-1:2016), BS 2982:1992.

Device(s) covered by this declaration:

Product Category	Class IIa Surgical Instruments Class I Sterile devices Class I Reusable instrument					
Products name, Classification, Rule, GMDN, EMDN codes and Basic UDI-DI.	**Product Name**	**Class**	**Rule**	**GMDN Codes**	**EMDN Codes**	**Basic UDI-DI**
	Surgical Blades (Sterile & Non-sterile) / Scalpel Blade	IIa	6	37445	V0103	8903376SBWT
	Disposable scalpels including safety type (Sterile &Non-sterile) / Sterile Scalpel	IIa	6	47569	V0101, V010101	8903376DSWG
	Dermal Curettes (Sterile & Non-sterile) /	IIa	6	63259	A01020303	8903376DCVG
	Biopsy Punch (Sterile & Non-sterile)	IIa	6	63028	A01020302	8903376BPW4
	Stitch Cutters (Sterile)	Is	1	63487	V0199	8903376SCWV
	Reusable Handle (Non-Sterile)	Ir	1	12235	L010103	8903376RHX4
MDN Code	1208					
MDS code(s)	1005-4 and 1006					
MDT code(s)	2001, MDT 2002, MDT 2008 and 2011					
Type of devices	Product List (Annex 1.1 of Technical File) DoC					
Intended Purpose	Product List (Annex 1.1 of Technical File) DoC					

Declaration of Conformity

Annex 1.1-Product List **Customer Name:** GIMA

Brand Name **GIMA**

Intended Purpose: The intended purpose of surgical blades is to make surgical incisions, cutting, scraping required during surgical and other minor procedures.

Mfr. Code	Mfg.Size	Customer Product REF.	Product Description	UDI/GTIN/EAN No.
02758	10	27000	Gima Surgical Blades Carbon Steel Sterile #10	18903376027581
02759	11	27001	Gima Surgical Blades Carbon Steel Sterile #11	18903376027598
02760	12	27002	Gima Surgical Blades Carbon Steel Sterile #12	18903376027604
02761	15	27003	Gima Surgical Blades Carbon Steel Sterile #15	18903376027611
02762	20	27004	Gima Surgical Blades Carbon Steel Sterile #20	18903376027628
02763	21	27005	Gima Surgical Blades Carbon Steel Sterile #21	18903376027635
02764	22	27006	Gima Surgical Blades Carbon Steel Sterile #22	18903376027642
02765	23	27007	Gima Surgical Blades Carbon Steel Sterile #23	18903376027659
02766	24	27008	Gima Surgical Blades Carbon Steel Sterile #24	18903376027666
02816	15C	27009	Gima Surgical Blades Carbon Steel Sterile #15C	18903376028168

Brand Name **Razormed**

Intended Purpose: The intended purpose of Stitch Cutter is to facilitate suture removal required during surgical procedures by cutting the suture stitches

Mfr. Code	Mfg.Size	Customer Product REF.	Product Description	UDI/GTIN/EAN No.
03019	SC	03019	Razormed, Long Stitch Cutter(DS),Stainless Steel, Sterile 10ea/Bx #SC	18903376030192

Brand Name **SAFhandle**

Intended Purpose: For surgical incisions

Mfr. Code	Mfg.Size	Customer Product REF.	Product Description	UDI/GTIN/EAN No.
00337	10SF	00337	SAFhandle Stainless Steel with Safety Scalpel Blade, Sterile# 10SF	18903376003370
00338	15SF	00338	SAFhandle Stainless Steel with Safety Scalpel Blade, Sterile# 15SF	18903376003387
00339	20SF	00339	SAFhandle Stainless Steel with Safety Scalpel Blade, Sterile# 20SF	18903376003394
00340	21SF	00340	SAFhandle Stainless Steel with Safety Scalpel Blade, Sterile# 21SF	18903376003400
00341	22SF	00341	SAFhandle Stainless Steel with Safety Scalpel Blade, Sterile# 22SF	18903376003417
00342	23SF	00342	SAFhandle Stainless Steel with Safety Scalpel Blade, Sterile# 23SF	18903376003424
00343	24SF	00343	SAFhandle Stainless Steel with Safety Scalpel Blade, Sterile# 24SF	18903376003431

Brand Name **GIMA**

Intended Purpose: The intended purpose of Disposable scalpel (including safety types) is to make surgical incisions, cutting, scraping required during surgical and other minor procedures.

Mfr. Code	Mfg.Size	Customer Product REF.	Product Description	UDI/GTIN/EAN No.
03241	10	27060	ECO Disposable Scalpels N.10 Box 10 Pcs.	18903376032417
03242	11	27061	ECO Disposable Scalpels N.11 Box 10 Pcs.	18903376032424
03243	12	27062	ECO Disposable Scalpels N.12 Box 10 Pcs.	18903376032431
03244	15	27063	ECO Disposable Scalpels N.15 Box 10 Pcs.	18903376032448
03245	20	27064	ECO Disposable Scalpels N.20 Box 10 Pcs.	18903376032455
03246	21	27065	ECO Disposable Scalpels N.21 Box 10 Pcs.	18903376032462
03247	22	27066	ECO Disposable Scalpels N.22 Box 10 Pcs.	18903376032479
03248	23	27067	ECO Disposable Scalpels N.23 Box 10 Pcs.	18903376032486
03249	24	27068	ECO Disposable Scalpels N.24 Box 10 Pcs.	18903376032493

Brand Name **GIMA**

Intended Purpose: The intended purpose of Disposable scalpel (including safety types) is to make surgical incisions, cutting, scraping required during surgical and other minor procedures.

Mfr. Code	Mfg.Size	Customer Product REF.	Product Description	UDI/GTIN/EAN No.
03506	10	27070	Sterile Safety Protective Shield Scalpels Fig.10	18903376035067
03507	11	27071	Sterile Safety Protective Shield Scalpels Fig.11	18903376035074
03509	15	27073	Sterile Safety Protective Shield Scalpels Fig.15	18903376035098
03510	20	27074	Sterile Safety Protective Shield Scalpels Fig.20	18903376035104
03511	21	27075	Sterile Safety Protective Shield Scalpels Fig.21	18903376035111
03512	22	27076	Sterile Safety Protective Shield Scalpels Fig.22	18903376035128
03513	23	27077	Sterile Safety Protective Shield Scalpels Fig.23	18903376035135
03514	24	27078	Sterile Safety Protective Shield Scalpels Fig.24	18903376035142

Brand Name **Razormed**

Intended Purpose: The intended purpose of Disposable scalpel (including safety types) is to make surgical incisions, cutting, scraping required during surgical and other minor procedures.

Mfr. Code	Mfg.Size	Customer Product REF.	Product Description	UDI/GTIN/EAN No.
01719	10	01719	Razormed Safety Scalpel with protective shield, non-sterile,10	18903376017193
01720	10S	01720	Razormed Safety Scalpel with protective shield, non-sterile,10S	18903376017209
01721	11	01721	Razormed Safety Scalpel with protective shield, non-sterile,11	18903376017216
01722	11K	01722	Razormed Safety Scalpel with protective shield, non-sterile,11K	18903376017223
01723	11P	01723	Razormed Safety Scalpel with protective shield, non-sterile,11P	18903376017230
01724	11PA	01724	Razormed Safety Scalpel with protective shield, non-sterile,11PA	18903376017247
01725	12s	01725	Razormed Safety Scalpel with protective shield, non-sterile,12	18903376017254

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01726	15C	01726	Razormed Safety Scalpel with protective shield, non-sterile,15C	18903376017261
01727	15	01727	Razormed Safety Scalpel with protective shield, non-sterile,15	18903376017278
01728	15S	01728	Razormed Safety Scalpel with protective shield, non-sterile,15S	18903376017285

Brand Name
Razormed

Intended Purpose: The intended purpose of Disposable scalpel (including safety types) is to make surgical incisions, cutting, scraping required during surgical and other minor procedures.

Mfr. Code	Mfg.Size	Customer Product REF.	Product Description	UDI/GTIN/EAN No.
01729	18	01729	Razormed Safety Scalpel with protective shield, non-sterile,18	18903376017292
01730	19	01730	Razormed Safety Scalpel with protective shield, non-sterile,19	18903376017308
01731	20	01731	Razormed Safety Scalpel with protective shield, non-sterile,20	18903376017315
01732	21	01732	Razormed Safety Scalpel with protective shield, non-sterile,21	18903376017322
01733	22	01733	Razormed Safety Scalpel with protective shield, non-sterile,22	18903376017339
01734	23	01734	Razormed Safety Scalpel with protective shield, non-sterile,23	18903376017346
01735	24	01735	Razormed Safety Scalpel with protective shield, non-sterile,24	18903376017353
01736	25	01736	Razormed Safety Scalpel with protective shield, non-sterile,25	18903376017360

Brand Name
GIMA

Intended Purpose: The intended purpose of surgical blades is to make surgical incisions, cutting, scraping required during surgical and other minor procedures.

Mfr. Code	Mfg.Size	Customer Product REF.	Product Description	UDI/GTIN/EAN No.
02767	10	27020	Gima, Surgical Blades,Stainless,Sterile,10	18903376027673
02768	11	27021	Gima, Surgical Blades,Stainless,Sterile,11	18903376027680
02769	12	27022	Gima, Surgical Blades,Stainless,Sterile,12	18903376027697
02770	15	27023	Gima, Surgical Blades,Stainless,Sterile,15	18903376027703
02771	20	27024	Gima, Surgical Blades,Stainless,Sterile,20	18903376027710
02772	21	27025	Gima, Surgical Blades,Stainless,Sterile,21	18903376027727
02773	22	27026	Gima, Surgical Blades,Stainless,Sterile,22	18903376027734
02774	23	27027	Gima, Surgical Blades,Stainless,Sterile,23	18903376027741
02775	24	27028	Gima, Surgical Blades,Stainless,Sterile,24	18903376027758

Brand Name
Diamantine

Intended Purpose: The intended purpose of surgical blades is to make surgical incisions, cutting, scraping required during surgical and other minor procedures.

Mfr. Code	Mfg.Size	Customer Product REF.	Product Description	UDI/GTIN/EAN No.
00941	10DM	00941	Diamantine High Performance Scalpel Blades,Stainless,sterile 100 pk#10DM	18903376009419
00942	11DM	00942	Diamantine High Performance Scalpel Blades,Stainless,sterile 100 pk#11DM	18903376009426
00943	12DM	00943	Diamantine High Performance Scalpel Blades,Stainless,sterile 100 pk#12DM	18903376009433
00944	15DM	00944	Diamantine High Performance Scalpel Blades,Stainless,sterile 100 pk#15DM	18903376009440
00945	20DM	00945	Diamantine High Performance Scalpel Blades,Stainless,sterile 100 pk#20DM	18903376009457
00946	21DM	00946	Diamantine High Performance Scalpel Blades,Stainless,sterile 100 pk#21DM	18903376009464
00947	22DM	00947	Diamantine High Performance Scalpel Blades,Stainless,sterile 100 pk#22DM	18903376009471
00948	23DM	00948	Diamantine High Performance Scalpel Blades,Stainless,sterile 100 pk#23DM	18903376009488
00949	24DM	00949	Diamantine High Performance Scalpel Blades,Stainless,sterile 100 pk#24DM	18903376009495
00950	25DM	00950	Diamantine High Performance Scalpel Blades,Stainless,sterile 100 pk#25DM	18903376009501
04201	15CDM	04201	Diamantine High Performance Scalpel Blades,Stainless,sterile 100 pk#15CDM	18903376042010

Brand Name
SAFhandle

Intended Purpose: For surgical incisions

Mfr. Code	Mfg.Size	Customer Product REF.	Product Description	UDI/GTIN/EAN No.
00688	3_	00688-SAFh-3	SAFhandle Safety Reusable Scalpel Handle, Stainless, Non-sterile#3	18903376006883
00689	4_	00689-SAFh-4	SAFhandle Safety Reusable Scalpel Handle, Stainless, Non-sterile#4	18903376006890

Brand Name
Razormed

Intended Purpose: The intended purpose of Disposable scalpel (including safety types) is to make surgical incisions, cutting, scraping required during surgical and other minor procedures.

Mfr. Code	Mfg.Size	Customer Product REF.	Product Description	UDI/GTIN/EAN No.
03771	10	03771	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#10	18903376037719
03772	10A	03772	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#10A	18903376037726
03773	10S	03773	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#10S	18903376037733
03774	11	03774	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#11	18903376037740
03775	11K	03775	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#11K	18903376037757
03776	11P	03776	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#11P	18903376037764
03777	11PA	03777	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#11PA	18903376037771
03778	12	03778	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#12	18903376037788
03779	12D	03779	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#12D	18903376037795
03780	15	03780	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#15	18903376037801
03781	15C	03781	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#15C	18903376037818
03782	15S	03782	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#15S	18903376037825
03783	18	03783	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#18	18903376037832
03784	19	03784	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#19	18903376037849

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03785	20	03785	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#20	18903376037856
03786	21	03786	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#21	18903376037863
03787	22	03787	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#22	18903376037870
03788	23	03788	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#23	18903376037887
03789	24	03789	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#24	18903376037894
03790	25	03790	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#25	18903376037900

Brand Name
Razormed

Intended Purpose: The intended purpose of Disposable scalpel (including safety types) is to make surgical incisions, cutting, scraping required during surgical and other minor procedures.

Mfr. Code	Mfg.Size	Customer Product REF.	Product Description	UDI/GTIN/EAN No.
03771	10	03771	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#10	18903376037719
03772	10A	03772	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#10A	18903376037726
03773	10S	03773	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#10S	18903376037733
03774	11	03774	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#11	18903376037740
03775	11K	03775	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#11K	18903376037757
03776	11P	03776	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#11P	18903376037764
03777	11PA	03777	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#11PA	18903376037771
03778	12	03778	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#12	18903376037788
03779	12D	03779	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#12D	18903376037795
03780	15	03780	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#15	18903376037801
03781	15C	03781	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#15C	18903376037818
03782	15S	03782	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#15S	18903376037825
03783	18	03783	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#18	18903376037832
03784	19	03784	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#19	18903376037849
03785	20	03785	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#20	18903376037856
03786	21	03786	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#21	18903376037863
03787	22	03787	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#22	18903376037870
03788	23	03788	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#23	18903376037887
03789	24	03789	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#24	18903376037894
03790	25	03790	Razormed Premium Classic Scalpel, 50ea/pkt Non-Sterile#25	18903376037900

Brand Name
GIMA

Intended Purpose: The intended purpose of Disposable scalpel (including safety types) is to make surgical incisions, cutting, scraping required during surgical and other minor procedures.

Mfr. Code	Mfg.Size	Customer Product REF.	Product Description	UDI/GTIN/EAN No.
01190	10	27040	PRIMA STERILE DISP.SCALPELS N.10 S.S.BLADE + BLADE GUARD	18903376011900
01191	11	27041	PRIMA STERILE DISP.SCALPELS N.11 S.S.BLADE + BLADE GUARD	18903376011917
01192	12	27042	PRIMA STERILE DISP.SCALPELS N.12 S.S.BLADE + BLADE GUARD	18903376011924
01193	15	27043	PRIMA STERILE DISP.SCALPELS N.15 S.S.BLADE + BLADE GUARD	18903376011931
01194	20	27044	PRIMA STERILE DISP.SCALPELS N.20 S.S.BLADE + BLADE GUARD	18903376011948
01195	21	27045	PRIMA STERILE DISP.SCALPELS N.21 S.S.BLADE + BLADE GUARD	18903376011955
01196	22	27046	PRIMA STERILE DISP.SCALPELS N.22 S.S.BLADE + BLADE GUARD	18903376011962
01197	23	27047	PRIMA STERILE DISP.SCALPELS N.23 S.S.BLADE + BLADE GUARD	18903376011979
01198	24	27048	PRIMA STERILE DISP.SCALPELS N.24 S.S.BLADE + BLADE GUARD	18903376011986
01199	15C	27049	PRIMA STERILE DISP.SCALPELS N.15C S.S.BLADE + BLADE GUARD	18903376011993

Brand Name
Diamantine

Intended Purpose: The intended purpose of Disposable scalpel (including safety types) is to make surgical incisions, cutting, scraping required during surgical and other minor procedures.

Mfr. Code	Mfg.Size	Customer Product REF.	Product Description	UDI/GTIN/EAN No.
00903	10DM	00903	Diamantine, Premium Scalpels Stainless Steel Sterile#10DM	18903376009037
00904	11DM	00904	Diamantine, Premium Scalpels Stainless Steel Sterile#11DM	18903376009044
00905	15DM	00905	Diamantine, Premium Scalpels Stainless Steel Sterile#15DM	18903376009051
00906	20DM	00906	Diamantine, Premium Scalpels Stainless Steel Sterile#20DM	18903376009068
00907	21DM	00907	Diamantine, Premium Scalpels Stainless Steel Sterile#21DM	18903376009075
00908	22DM	00908	Diamantine, Premium Scalpels Stainless Steel Sterile#22DM	18903376009082
00909	23DM	00909	Diamantine, Premium Scalpels Stainless Steel Sterile#23DM	18903376009099
00910	24DM	00910	Diamantine, Premium Scalpels Stainless Steel Sterile#24DM	18903376009105

Brand Name
Razormed

Intended Purpose: The intended purpose of Disposable scalpel (including safety types) is to make surgical incisions, cutting, scraping required during surgical and other minor procedures.

Mfr. Code	Mfg.Size	Customer Product REF.	Product Description	UDI/GTIN/EAN No.
02887	10	02887	Razormed Retractable Safety Scalpel Stainless, Non-sterile#10	18903376028878
02888	10S	02888	Razormed Retractable Safety Scalpel Stainless, Non-sterile#10S	18903376028885
02889	11	02889	Razormed Retractable Safety Scalpel Stainless, Non-sterile#11	18903376028892
02890	11K	02890	Razormed Retractable Safety Scalpel Stainless, Non-sterile#11K	18903376028908
02891	11PA	02891	Razormed Retractable Safety Scalpel Stainless, Non-sterile#11PA	18903376028915
02892	11P	02892	Razormed Retractable Safety Scalpel Stainless, Non-sterile#11P	18903376028922
02893	15	02893	Razormed Retractable Safety Scalpel Stainless, Non-sterile#15	18903376028939

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02894	15C	02894	Razormed Retractable Safety Scalpel Stainless, Non-sterile#15C	18903376028946
02895	15S	02895	Razormed Retractable Safety Scalpel Stainless, Non-sterile#15S	18903376028953

RAZORMED INC. states that the Surgical Instruments covered by the present declaration is in conformity with the Regulation EU 2017/745.

Name: Ambuj Srivastav

Designation: General Manager, QA/RA and MR

Signature:

Print Date: 27/10/2026

Razormed Inc Gurugram