



# CE Declaration of Conformity

## CUSTOMER NAME

### GIMA SPA

VIA MARCONI, 1, 20060  
GESSATE (MI)  
Italy,  
Vat Nr: 00734640154

**Razormed Inc**  
B3 Infocity, Sector 33-34  
Gurgaon 122001  
Haryana- India

T +91 124 433 8888  
F +91 124 433 8800  
E info@razormed.com  
www.razormed.com

RAZORMED CODE	GIMA CODE	PRODUCT DESCRIPTION	PRODUCT CLASS
02758	27000	Gima, Surgical Blades,Carbon,Sterile,10	Class IIa
02759	27001	Gima, Surgical Blades,Carbon,Sterile,11	Class IIa
02760	27002	Gima, Surgical Blades,Carbon,Sterile,12	Class IIa
02761	27003	Gima, Surgical Blades,Carbon,Sterile,15	Class IIa
02762	27004	Gima, Surgical Blades,Carbon,Sterile,20	Class IIa
02763	27005	Gima, Surgical Blades,Carbon,Sterile,21	Class IIa
02764	27006	Gima, Surgical Blades,Carbon,Sterile,22	Class IIa
02765	27007	Gima, Surgical Blades,Carbon,Sterile,23	Class IIa
02766	27008	Gima, Surgical Blades,Carbon,Sterile,24	Class IIa
02816	27009	Gima, Surgical Blades,Carbon,Sterile,15C	Class IIa
03241	27060	ECO Disposable Scalpels N.10 Box 10 Pcs.	Class IIa
03242	27061	ECO Disposable Scalpels N.11 Box 10 Pcs.	Class IIa
03243	27062	ECO Disposable Scalpels N.12 Box 10 Pcs.	Class IIa
03244	27063	ECO Disposable Scalpels N.15 Box 10 Pcs.	Class IIa
03245	27064	ECO Disposable Scalpels N.20 Box 10 Pcs.	Class IIa
03246	27065	ECO Disposable Scalpels N.21 Box 10 Pcs.	Class IIa
03247	27066	ECO Disposable Scalpels N.22 Box 10 Pcs.	Class IIa
03248	27067	ECO Disposable Scalpels N.23 Box 10 Pcs.	Class IIa
03249	27068	ECO Disposable Scalpels N.24 Box 10 Pcs.	Class IIa
03506	27070	Sterile Safety Protective Shield Scalpels Fig.10	Class IIa
03507	27071	Sterile Safety Protective Shield Scalpels Fig.11	Class IIa
03509	27073	Sterile Safety Protective Shield Scalpels Fig.15	Class IIa
03510	27074	Sterile Safety Protective Shield Scalpels Fig.20	Class IIa
03511	27075	Sterile Safety Protective Shield Scalpels Fig.21	Class IIa
03512	27076	Sterile Safety Protective Shield Scalpels Fig.22	Class IIa
03513	27077	Sterile Safety Protective Shield Scalpels Fig.23	Class IIa
03514	27078	Sterile Safety Protective Shield Scalpels Fig.24	Class IIa
02767	27020	Gima, Surgical Blades,Stainless,Sterile,10	Class IIa
02768	27021	Gima, Surgical Blades,Stainless,Sterile,11	Class IIa
02769	27022	Gima, Surgical Blades,Stainless,Sterile,12	Class IIa
02770	27023	Gima, Surgical Blades,Stainless,Sterile,15	Class IIa
02771	27024	Gima, Surgical Blades,Stainless,Sterile,20	Class IIa
02772	27025	Gima, Surgical Blades,Stainless,Sterile,21	Class IIa
02773	27026	Gima, Surgical Blades,Stainless,Sterile,22	Class IIa
02774	27027	Gima, Surgical Blades,Stainless,Sterile,23	Class IIa
02775	27028	Gima, Surgical Blades,Stainless,Sterile,24	Class IIa
00941	27010	Diamantine High Performance Scalpel Blades, Stainless, sterile 100 pk#10DM	Class IIa
00942	27011	Diamantine High Performance Scalpel Blades, Stainless, sterile 100 pk#11DM	Class IIa
00944	27013	Diamantine High Performance Scalpel Blades, Stainless, sterile 100 pk#15DM	Class IIa
00945	27014	Diamantine High Performance Scalpel Blades, Stainless, sterile 100 pk#20DM	Class IIa
00946	27015	Diamantine High Performance Scalpel Blades, Stainless, sterile 100 pk#21DM	Class IIa
00947	27016	Diamantine High Performance Scalpel Blades, Stainless, sterile 100 pk#22DM	Class IIa
00948	27017	Diamantine High Performance Scalpel Blades, Stainless, sterile 100 pk#23DM	Class IIa
00949	27018	Diamantine High Performance Scalpel Blades, Stainless, sterile 100 pk#24DM	Class IIa
01190	27040	PRIMA STERILE DISP.SCALPELS N.10 S.S.BLADE + BLADE GUARD	Class IIa

01191	27041	PRIMA STERILE DISP.SCALPELS N.11 S.S.BLADE + BLADE GUARD	Class IIa
01192	27042	PRIMA STERILE DISP.SCALPELS N.12 S.S.BLADE + BLADE GUARD	Class IIa
01193	27043	PRIMA STERILE DISP.SCALPELS N.15 S.S.BLADE + BLADE GUARD	Class IIa
01194	27044	PRIMA STERILE DISP.SCALPELS N.20 S.S.BLADE + BLADE GUARD	Class IIa
01195	27045	PRIMA STERILE DISP.SCALPELS N.21 S.S.BLADE + BLADE GUARD	Class IIa
01196	27046	PRIMA STERILE DISP.SCALPELS N.22 S.S.BLADE + BLADE GUARD	Class IIa
01197	27047	PRIMA STERILE DISP.SCALPELS N.23 S.S.BLADE + BLADE GUARD	Class IIa
01198	27048	PRIMA STERILE DISP.SCALPELS N.24 S.S.BLADE + BLADE GUARD	Class IIa
01199	27049	PRIMA STERILE DISP.SCALPELS N.15C S.S.BLADE + BLADE GUARD	Class IIa
00903	22460	Diamantine, Premium Scalpels Stainless Steel Sterile#10DM	Class IIa
00904	22461	Diamantine, Premium Scalpels Stainless Steel Sterile#11DM	Class IIa
00905	22463	Diamantine, Premium Scalpels Stainless Steel Sterile#15DM	Class IIa
00906	22464	Diamantine, Premium Scalpels Stainless Steel Sterile#20DM	Class IIa
00907	22465	Diamantine, Premium Scalpels Stainless Steel Sterile#21DM	Class IIa
00908	22466	Diamantine, Premium Scalpels Stainless Steel Sterile#22DM	Class IIa
00909	22467	Diamantine, Premium Scalpels Stainless Steel Sterile#23DM	Class IIa
00910	22468	Diamantine, Premium Scalpels Stainless Steel Sterile#24DM	Class IIa

We **Razormed Inc.**, at B3 Infocity, Sector 33-34, Gurgaon, India, in accordance with the European Medical Device Directive

93/42/EEC do hereby declare that the above products conform to specifications and is in compliance with harmonized standards

EN BS 2982:1992, EN 27740:1992/AC:2016( ISO 7740: 1985), EN ISO 11607-1:2009, EN ISO 11607-2:2006, EN ISO 11737-1:2006/AC2009, BS EN 868-5:2018, EN ISO 10993-1:2009/AC:2010, EN ISO 10993-5:2009, EN ISO 10993-12:2012, EN ISO 10993-18:2009, EN ISO 11137-1&2:2015, EN 62366:2008, ISO 15223-1:2016, and those standards specified in its Quality System.

The company has selected DNV GL PRESAFE AS, as Notified Body and authorizes the Notified Body to carry out necessary inspection and agrees to supply the required information and data/documents from time to time. CE Certificate No. 10558-2017-CE-IND-NA-PS Rev. 1.0

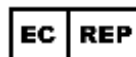
The Quality Management System of Razormed Inc., is certified by DNV GL PRESAFE AS (Notified Body No. 2460) for design, production and final product inspection/testing of Disposable Medical Devices and has been assessed with respect to the conformity assessment procedures described in article 11.3.a and Annex II, excluding section 4, of the Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply.

The company agrees to make available all document and data to national authority for a period ending at least seven (7) years after the last product has been manufactured.

The company and its authorized representative Advena Ltd, Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013, Malta shall fulfill the obligations imposed by MDD and ensure and declare that the company's products shall meet all provisions of the directive as applicable.

The company undertakes to keep up to date a systematic procedure to review experiences gained during post production phase and to implement through appropriate means necessary corrective and preventive action taking into account the nature and risk in relation to the product.

The company undertakes to notify immediately any malfunction/deterioration of the performance of the device to the appropriate authority and shall recall such devices already placed in the market.



**Advena Ltd.**

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

For and on behalf of Razormed Inc.

Ambuj Srivastav (General Manager QA/RA)

Date: 21/11/2019