

# 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

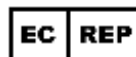
The Quality Management System of Razormed Inc., is certified by DNV GL PRESAFE AS (Notified Body No. 2460) for design, production and final product inspection/testing of Disposable Medical Devices and has been assessed with respect to the conformity assessment procedures described in article 11.3.a and 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