

Declaration of Conformity

RazormedTM

CUSTOMER NAME

GIMA SPA

Via MARCONI, 1
20060 GESSATE (MI)
Italy
VAT Nr: IT 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

Product Description:

Non Sterile, Stainless Steel, SAFhandle Safety Reusable scalpel handle, packed in poly pouch.	LOT NO(s) 1473963, 13132977, 14203691	Quantity 216 Unit Box of 1 pcs. each
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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 ISO 27740 and those standards specified in its Quality System (The above listed product are in Class 1 as per MDD 93/42/EEC).

Razormed Inc. is certified by Det Norske Veritas for conformance to the Quality System Standard(s) ISO 9001: 2008/ ISO 13485: 2003/ NS-EN ISO 13485: 2012 (Certificate No. 183537-2015-AQ-IND-NA, original certificate valid upto 2018-07-02). This certificate is valid for the following product or service ranges, "Design and Development, Procurement, Manufacture and Supply of Surgical and Skin Graft Blades, Disposable Scalpels and Stitch Cutters, Reusable Handles, Disposable Lancet for Heel Incision and Disposable Biopsy Punch.

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.

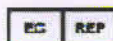
The company and its authorized representative Albion Surgicals Limited, Aizlewood's Mill, Nursery Street, Sheffield S3 8GG, UK shall fulfill the obligations imposed by MDD and ensure and declare that the company's products shall meet all provisions of the directive as applicable.

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.

For and on behalf of Razormed Inc.

Ambuj Srivastav
General Manager
QA/RA & MR



Albion Surgicals Limited

Aizlewood's Mill, Nursery Street
Sheffield, S3 8GG England.
Email: info@albionsurgicals.com

Dated: 01-October-2015

