DNV BUSINESS ASSURANCE

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 4743-2007-CE-NOR
This Certificate consists of 4 pages

This is to certify that the Quality Management System of

Razormed Inc.

B-3 Info City, Sector 33-34 Gurgaon, Haryana-122001, India

for design, production and final product inspection/testing of

Disposable Medical Devices

has been assessed with respect to
the conformity assessment procedure described in Article 11.5 and Annex V ((Module D) of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

Further details are given overleaf

Place and date:
Høvik, 06 July 2012

For DET NORSKE VERITAS CERTIFICATION AS
NORWAY

Aud Løken Eiklid
Certification Manager

NORWEGIAN ACCREDITATION
PROD 002

Notified Body No.:
0434

This Certificate is valid until:
04 July 2017

Cecilie Gudesen Torp
Technical Reviewer

This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info

Notice: The certificate is subject to terms and conditions overleaf. Any significant changes in design or construction may render this certificate invalid.

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as 'Forskrift for Medisinsk Utstyr' by the Norwegian Ministry of Health and Care Services.

Certificate history

Revision	Description	Issue Date
	Original certificate	2007-07-04
	Recertification	**2012-07-04**

Products covered by this Certificate

Product Description	Product/ Model	Class
Sterile & Non Sterile Surgical Blades in Carbon Steel & Stainless Steel	Sizes: 1,2,3,4,5,6,7,8, 9,10,10A,11,11P,11PA,11K,12,12A,12B,12D,13,14,15, 15A,15B,15C,15S,16,17,18,19,20,21,22,23,24,25,36,60,60B. 10DM,11DM,12DM,12BDM,15DM,15CDM,15SDM,18DM,19DM,20DM, 21DM,22DM,23DM,24DM, 36DM,60DM. 10SFD,15SFD, 20 SFD,21SFD,22SFD,23SFD,24 SFD,36SFD,60SFD. 10SF,15SF,18SF,19SF,20SF,21SF,22SF,23SF,24SF ,36SF,60SF 10OP,11OP,11OPL,18OP,19OP,20OP,21OP,22OP,23OP,24OP,36OP,60OP 11H	IIa
Sterile & Non Sterile Disposable Scalpels in Carbon Steel & Stainless Steel	Sizes: 1,2,3,4,5,6,7,8, 9,10,10A,11,11P,11PA,11K,12,12A,12B,12D,13,14,15, 15A,15B,15C,15S,16,17,18,19,20,21,22,23,24,25,36,60,60B. 10DM,11DM,12DM,12BDM,15DM,15CDM,15SDM,18DM,19DM,20DM, 21DM,22DM,23DM,24DM, 36DM,60DM. 10SFD,15SFD, 20SFD, 21SFD,22SFD,23SFD,24SFD,36SFD,60SFD. 10SF,15SF,18SF,19SF,20SF,21SF,22SF,23SF,24SF ,36SF,60SF 10OP,11OP,11OPL,18OP,19OP,20OP,21OP,22OP,23OP,24OP,36OP,60OP 11H	IIa
Sterile & Non Sterile Dental Disposable Scalpelin Carbon Steel & Stainless Steel	Sizes: 1,2,,3,4,5,6,7,8,9,10,10A,10S,11,11P,11K,12,12A,12B,12D,13,14,15,15A, 15B,15C,15S,15T, 10SF,15SF	IIa
Sterile & Non Sterile Disposable Mini Scalpels in Carbon Steel & Stainless Steel	Sizes: 1,2,3,4,5,6,7,8,9,10,10A,10S,11,11P,11K,12,12A,12B,12D,13,14,15,15A, 15B,15C,15S,15T, 10SF,15SF	IIa
Sterile & Non Sterile Surgical Blades Gouge and Curette Type in Carbon Steel & Stainless Steel	Sizes: 1, 2, 3, 4, 5, 6,7, 8, 10, 11,12, 15 ,32,34,36	IIa

Sterile & Non Sterile Disposable Safety Scalpels in Carbon Steel & Stainless Steel	Sizes: 1,2,3,4,5,6,7,8, 9,10,10A,11,11P,11PA,11K,12,12A,12B,12D,13,14,15, 15A,15B,15C,15S,16,17,18,19,20,21,22,23,24,25,36,60,60B. 10DM,11DM,12DM,12BDM,15DM,15CDM,15SDM,18DM,19DM,20DM, 21DM,22DM,23DM,24DM, 36DM,60DM. 10SFD,15SFD, 20SFD,21SFD,22SFD,23SFD,24SFD,36SFD,60SFD. 10SF,15SF,18SF,19SF,20SF,21SF,22SF,23SF,24SF ,36SF,60SF 10OP,11OP,11OPL,18OP,19OP,20OP,21OP,22OP,23OP,24OP,36OP,60OP 11H	IIa
Sterile & Non Sterile Disposable Thumb Scalpel in Carbon Steel & Stainless Steel	1,2,3,4,5,6,7,8,9, 10, 10A, 10S, 11, 11P,11K, 12, 12A,12B, 12D, 13, 14, 15, 15A, 15B, 15C,15S, 15T,10SF,15 SF	IIa
Sterile Stitch Cutter Blades in Carbon Steel & Stainless Steel	Small Blade, Medium Blade, Standard Stich Cutter, Long Blade, Long Stich Cutter with Plastic Handle and blade Guard, Safety Stich Cutter Scalpel	Is
Sterile & Non Sterile Skin Graft Blades in Carbon Steel & Stainless Steel	Standard	IIa
Sterile Biopsy PunchesStainless Steel	Size: 2 mm, 3 mm, 4 mm, 6 mm, 8.0 mm	IIa
Sterile Heel Incision Device Stainless Steel	Size: Depth Length 0.65 mm 1.40 mm 0.85 mm 1.75 mm 1.00 mm 2.5 mm 2.00 mm 3.00 mm	IIa
Sterile & Non Sterile Disposable Scalpel Long Handle in Carbon Steel & Stainless Steel	Size: 10,10A,11,11P,11K,12,12A,12B,12D,13,14,15,15A,15B,15C,15S,15T,16,17, 18,19,20,21,22A,22,23,24,24D,25,25A 10SF,15SF,21SF,22SF,23SF,24SF,25SF,36SF,60SF	IIa

The complete list of devices is filed with the Notified Body.

Sites covered by this certificate:

Razormed Inc., B-3 Info City, Sector 33-34 Gurgaon, Haryana-122001, India

EU Representative: Albion Surgicals Limited, Sheffield S3 8GG, UNITED KINGDOM

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the local DNV Office of any intended updating of the quality system and DNV will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system DNV reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of DNV.

END OF CERTIFICATE