License Number : IL/MD-000803 - RC/MD-000261
DATED :29-Dec-2017 VALID UPTO :20-Dec-2020 File Number : IMP/Form8/MD/2017/15806

सत्यमेव जयते

GOVERNMENT OF INDIA

Ministry of Health & Family Welfare

Central Drugs Standard Control Organisation

FDA BHAWAN, NEW DELHI (INDIA)

LIST OF MEDICAL DEVICES WHICH MAY BE IMPORTED UNDER IMPORT LICENCE NO. IL/MD-000803 - RC/MD-000261 DATED 29-Dec-2017 VALID UPTO 20-Dec-2020

S.NO	Notified Category	Device Details
1	Wound Dressings	**A. Generic Name:** Absorbable Gelatin Hemostat **B. Brand Name :** GELITA **C. Model No.:** GELITA - SPON STANDARD (GS 003/GS 004/GS 010 SP/GS 010 DP/GS 015/GS 030/GS 060/GS 110/GS 210/GS 310/GS 325/GS 610/GS 950), GELITA - SPON RAPID3 (GR 005/GR 007/GR 010/GR 310/GR 610), GELITA - SPON POWDER (GS 265), GELITA TUFT - IT (GF 7365) **D. Components:** NIL **E. Contains Drug:** No **F. Intended Use:** Hemostat for use as an adjunct to hemostasis by tamponade effect, in particular where control of capillary, venous, and arteriolar bleeding, by pres- sure, ligature, and other conventional procedures, is either ineffective or impractical. **G. Shelf life:** 5.00 Years
2	Wound Dressings	**A. Generic Name:** Absorbable Cellulose Hemostat **B. Brand Name :** GELITA **C. Model No.:** GELITA - CEL X SORB (GX 603/GX 608/GX 609/GX 610/GX 620) ,GELITA - CEL FIBRILLAR (GF 705/GF 708/GF 710/GF 711) ,GELITA - CEL STANDARD (GC 501/GC 507/GC 510/GC 535/GC 540) **D. Components:** NIL **E. Contains Drug:** No **F. Intended Use:** Hemostat for use in capillary bleeding of venous Or arteriolar origin. **G. Shelf life:** 36.00 Months

VENUGOPAL

Digitally signed by VENUGOPAL GIRDHARILAL

DEKRA

ADDENDUM

Belonging to certificate: 2141242DE01

EC DESIGN-EXAMINATION
MEDICAL DEVICES

Nonactive implants: Absorbable Gelatin Sponge and Non-Woven Hemostat

Issued to:

GELITA MEDICAL GmbH
Uferstrasse 7
69412 Eberbach
Germany

This certificate covers the following product(s):

Addendum 1:

- GELITA-SPON® STANDARD
- GELITA-SPON® RAPID3
- GELITA-SPON® POWDER
- GELITA-SPON® RAPID3 HD ENT
- GELITA TUFT-IT

DEKRA Certification B.V.

Managing Director

J.A. van Vugt
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

BOHR

Bohr Scientific (P) Ltd
OFFICE NO.:-5, G.F, NG-12,
JWALA HERI, PASCHIM VIHAR
NEW DELHI -110063
M: - 9871996432, 011-25217147
DL: - MDP-110092/93 -20B, 21B
GSTIN: - 07AAGCB6240G1ZV

Date :-30/11/2018

To

The HOD
Dept. of Neurosurgery
CNC AIIMS
New Delhi

Respected Sir

Here by I am submitting the following documents of GELITA TUFT IT & GELITA RAPID Spong

1. Proprietary Certificate
2. Porforma Invoice
3. Rate Justification order Copy
4. Patent certificate
5. CE Certificate

Kindly acknowledge the same

Best Regards

BOHR SCIENTIFIC PVT LTD.

File Number : IMP/Form8/MD/2017/15806

Form 10
(See rules 23 and 27)

Licence to import devices (excluding those specified in Schedule X) to the Drugs and Cosmetics Rules, 1945

Date : **29-Dec-2017**

License Number : IL/MD-000803 - RC/MD-000261

1. **M/s Cardiomed India Ltd., Office No.-108 Ist Floor, Property No-29, Firoj Gandhi Link Road, Lajpat Nagar III, Delhi (India) - 110024** is hereby licensed to import into India during the period for which this licence is in force, the devices specified below, manufactured by **M/s. GELITA MEDICAL GmbH, Uferstrasse 7, 69412 Eberbach, Germany (Germany)** having actual manufacturing premises at **M/s. GELITA AG, Gammelsbacher Str. 2, 69412 Eberbach, Germany (Germany)** and any other device manufactured by the said manufacturer as may from time to time be endorsed on this licence.
2. This licence shall be in force from **29-Dec-2017** to **20-Dec-2020** unless it is sooner suspended or cancelled under the said rules.
3. **Name of the devices to be imported**

As per list enclosed

Item(s) Three Only

VENUGOPAL GIRDHARILAL SOMANI

Digitally signed by VENUGOPAL GIRDHARILAL SOMANI
Date: 2017.12.29 21:17:00 +05'30'

LICENSING AUTHORITY

Place: **New Delhi**

Date : **29-Dec-2017**

Seal/Stamp

Conditions of License

1. A photocopy of licence shall be displayed in a prominent place in a part of the premises, and the original licence shall be produced, whenever required.
2. Each batch of drug imported into India shall be accompanied with a detailed batch test report and a batch release certificate, duly signed and authenticated by the manufacturer with date of testing, date of release and date of forwarding such reports. The imported batch of each drug shall be subjected to examination and testing as the licensing authority deems fit prior to its marketing.
3. The licensee shall be responsible for the business activities of the manufacturer in India along with the registration holder and his authorized agent.
4. The licensee shall inform the licensing authority forthwith in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution.

CARDIOMED INDIA LIMITED
108, 28-29, LINK ROAD, F.G. MARG, LAJPAT NAGAR-III
NEW DELHI-110024

GELITA®
MEDICAL
Complete Care! Completely Safe!

This product list belongs to the Declaration of Conformity identified by GELITA MEDICAL GmbH and specifies the CE marked products that GELITA MEDICAL GmbH intends to distribute in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

The following list identifies the products by Device Name and sizes.

Device Name	Product information		
	REF	Quantity	Size
GELITA-SPON® STANDARD			
GELITA-SPON® STANDARD	GS-002	(Qty 2)	80 x 50 x 10 mm
GELITA-SPON® STANDARD	GS-003	(Qty 4 x 50)	3 x 2 x 2 mm
GELITA-SPON® STANDARD	GS-004	(Qty 4 x 25)	4 x 4 x 4 mm
GELITA-SPON® STANDARD	GS-010 DP	(Qty 10)	80 x 50 x 10 mm
GELITA-SPON® STANDARD	GS-010 SP	(Qty 10)	80 x 50 x 10 mm
GELITA-SPON® STANDARD	GS-015	(Qty 10)	80 x 50 x 10 mm high density
GELITA-SPON® STANDARD	GS-030	(Qty 10)	80 x 40 x 10 mm
GELITA-SPON® STANDARD	GS-060	(Qty 10)	60 x 20 x 7 mm
GELITA-SPON® STANDARD	GS-310	(Qty 50)	10 x 10 x 10 mm
GELITA-SPON® STANDARD	GS-325	(Qty 50)	10 x 10 x 10 mm high density
GELITA-SPON® STANDARD	GS-110	(Qty 20)	80 x 50 x 1 mm
GELITA-SPON® STANDARD	GS-950	(Qty 20)	200 x 70 x 0.5 mm
GELITA-SPON® STANDARD	GS-610	(Qty 10)	125 x 80 x 10 mm
GELITA-SPON® STANDARD	GS-210	(Qty 5)	80 x diam 30 mm
GELITA-SPON® RAPID²			
GELITA-SPON® RAPID²	GR-005	(Qty 10)	80 x 25 x 4 mm
GELITA-SPON® RAPID²	GR-010	(Qty 10)	80 x 50 x 4 mm
GELITA-SPON® RAPID²	GR-310	(Qty 50)	10 x 10 x 4 mm
GELITA-SPON® RAPID²	GR-610	(Qty 10)	125 x 80 x 4 mm
GELITA-SPON® RAPID² HD ENT			
GELITA-SPON® RAPID² HD ENT	GR-007	(Qty 10)	80 x 15 x 7 mm
GELITA-SPON® POWDER			
GELITA-SPON® POWDER	GS-265	(Qty 4)	1 gram
GELITA TUFT-IT®			
GELITA TUFT-IT®	GF-7365	(Qty 10)	75 x 50 mm

CARDIOMED INDIA LIMITED
108, 28-29,
LINK ROAD,
F.G. MARG,
LAJPAT
NAGAR-III

DEKRA

ADDENDUM

Belonging to certificate: 2141242DE01

EC DESIGN-EXAMINATION
MEDICAL DEVICES

Nonactive implants: Absorbable Gelatin Sponge and Non-Woven Hemostat

Issued to:

GELITA MEDICAL GmbH
Uferstrasse 7
69412 Eberbach
Germany

Addendum 2:

- GELITA® ENT X-DENSE
- GELITA® ENT X-BLOD
- GELITA® ENT X-PAND
- GELITA® ENT X-PASTE

Initial date: 20 November 2015
Revision date: 21 November 2018

DEKRA Certification B.V.

Managing Director

J.A. van Vugt
Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

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(12) **Patent Application Publication** (10) **Pub. No.: US 2011/0071227 A1**
(43) **Pub. Date: Mar. 24, 2011**

Ahlers et al.

(54) **RAPIDLY WETTING MATERIAL CONTAINING HYDROCOLLOID, METHOD FOR THE MANUFACTURE THEREOF AND USE THEREOF**

(75) Inventors: **Michael Ahlers**, Eberbach (DE); **Steffen Oesser**, Glucksburg (DE); **Michael Grzinia**, Schwaikheim (DE); **Klaus Flechsenhar**, Eberbach (DE)

(73) Assignee: **GELITA AG**, Eberbach (DE)

(21) Appl. No.: **12/897,255**

(22) Filed: **Oct. 4, 2010**

Related U.S. Application Data

(63) Continuation of application No. PCT/EP2009/054452, filed on Apr. 15, 2009.

(30) **Foreign Application Priority Data**

Apr. 15, 2008 (DE) 10 2008 020 197.9

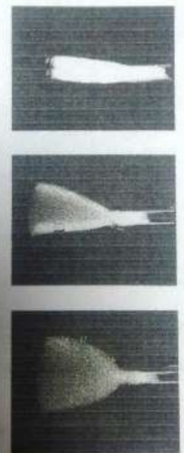
Publication Classification

(51) **Int. Cl.**
A61K 47/42 (2006.01)
B01J 20/00 (2006.01)
B01J 20/24 (2006.01)
B01J 20/22 (2006.01)

(52) **U.S. Cl.** **514/774**; 502/400; 502/404; 502/405

(57) **ABSTRACT**

The present invention relates to a method for the production of a quickly wettable material containing natural hydrocolloid in the form of a shaped body, in which a material containing natural hydrocolloid in the form of a shaped body is exposed to a plasma.



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Four Wheeler Insurance Quotes

License Number : IL/MD-000803 - RC/MD-000261

DATED :29-Dec-2017 VALID UPTO :20-Dec-2020 File Number : IMP/Form8/MD/2017/15806

S.NO	Notified Category	Device Details
3	Wound Dressings	**A. Generic Name:** Absorbable Cellulose Hemostat **B. Brand Name :** GELITA **C. Model No.:** GELITA - CEL CA POWDER (GA 260) **D. Components:** NIL **E. Contains Drug:** No **F. Intended Use:** Hemostat for use in capillary bleeding of venous Or arteriolar origin. **G. Shelf life:** 5.00 Years

CENTRAL DRUGS STANDARD CONTROL ORGANISATION

CDSCO CDSCO

MINISTRY OF HEALTH, GOVERNMENT OF INDIA

CARDIOMED INDIA LIMITED
108, 29, LINK ROAD, F.C. MARG, LAJPAT NAGAR-III
NEW DELHI-110024

Cardiomed INDIA

October 15th , 2018

To,
The Chief,
CNC,
AIIMS,
New Delhi.

Dear Sir,

Cardiomed India Ltd. is the sole importer for Gelita Surgical Hemostats manufactured by Gelita Medical, Germany.

Cardiomed has appointed M/s Bohr Scientific Pvt.Ltd. with offices at:

#5, NG-12 GF, Jawala Heri Market,
Paschim Vihar, New Delhi 110063

as our authorized distributor for Gelita Medical, Germany for All India Institute of Medical Science, New Delhi.

This authorization is valid till 14th October 2020.

For Cardiomed India Ltd.

Vevake Dean
Managing Director

108, 28-29, Link Road, Jeevan Gandhi Marg, Lajpat Nagar-III, New Delhi - 110024. Tel : +91-11-41 515 Fax : +91-11-41
E-mail : customersupport@cardiomedindia.com Website : www.cardiomedindia.com

PROFORMA INVOICE

CARDIOMED INDIA LTD.

108, 28-29, Link Road, Feroze Gandhi Marg,
Lajpat Nagar III, New Delhi-110 024
Tel. : +91-11-29838549, 29840210
Email: customersupport@cardiomedindia.com

To:
THE CHIEF
CNC
AIIMS,
ANSARI NAGAR, NEW DELHI-

Date : 26th Dec. 2018
Proforma Invoice No. : 930
Challan No. :
Order No. :
Order Date :
Payment :
Dispatch :

Customers Tax Details

S.No.	Description	Rate (Rs.)	Qty	HSN	Amount (Rs.)
1	GF-7365 Gelita Tuft-It 50x75mm	3600	1	30059090	3,600.00

Terms and Conditions:
1.GST Extra as applicable
2.Delivery : Within 30 days
3.Price FOR New Delhi

Total Amount	3,600.00
GST as Applicable @5 %	180.00
Total	3,780.00

Rs. Four Thousand Eight Hundred Forty Five & Forty Six Paise

GST NO. 07AAABCC6062A2Z2
PAN NO. AABCC6062A

Drug Licence No. 14(333)Dtd 27/04/2009

E.&.O.E

Receiver's Signature

For CARDIOMED INDIA LTD.

Authorised Signatory

EC CERTIFICATE

Number: 2141242CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:
GELITA MEDICAL GmbH
Uferstrasse 7
69412 Eberbach
Germany

For the product category(ies)

Sterile non-active non-woven porcine gelatin implants and wound dressings.

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2141242CN, initially dated 9 February 2011
Addendum, initially dated 9 February 2011

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 December 2018
Issued for the first time: 9 February 2011
Reissued: 1 December 2015

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

CARDIOMED INDIA LIMITED
108, 28-29, LINK ROAD, F.G. MAAG, LAJPAT NAGAR-IV, NEW DELHI-110024

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DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com

Cardiomed

October 15th , 2018

To,
The Chief,
CNC,
AIIMS,
New Delhi.

Dear Sir,

Cardiomed India Ltd. is the sole importer for Gelita Surgical Hemostats manufactured by Gelita Medical, Germany.

Cardiomed has appointed M/s Bohr Scientific Pvt.Ltd. with offices at:

#5, NG-12 GF, Jawala Heri Market,
Paschim Vihar, New Delhi 110063

as our authorized distributor for Gelita Medical, Germany for All India Institute of Medical Science, New Delhi.

This authorization is valid till 14th October 2020.

For Cardiomed India Ltd.

Vevake Dean
Managing Director

Fax : +91-11-41716615
Website : www.cardiomedindia.com

ADDENDUM

Belonging to certificate: 2141242CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Sterile non-active non-woven porcine gelatin implants and wound dressings.

Issued to:

GELITA MEDICAL GmbH
Uferstrasse 7
69412 Eberbach
Germany

Addendum 2: Class III, GELITA Absorbable Gelatin Hemostat:

- GELITA® ENT X-DENSE
- GELITA® ENT X-BLOD
- GELITA® ENT X-PAND
- GELITA® ENT X-PASTE

Initial date: 9 February 2011
Revision date: 17 March 2016

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

CARDIOMED INDIA LIMITED
108, 28-29, LINK ROAD, F.C. MARG, LAJPAT NAGAR-III, NEW DELHI-110024

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Inventors list Assignees list Classification tree browser Top 100 Inventors Top 100 Assignees

Patent application title: RAPIDLY WETTING MATERIAL CONTAINING HYDROCOLLOID, METHOD FOR THE MANUFACTURE THEREOF AND USE THEREOF

Inventors: Michael Ahlers (Eberbach, DE) Steffen Oesser (Glucksburg, DE) Michael Grzinia (Schwaikheim, DE) Klaus Flechsenhar (Eberbach, DE)
Assignees: GELITA AG
IPC8 Class: AA61K4742FI
USPC Class: 514774
Class name: Designated organic nonactive ingredient containing other than hydrocarbon peptide containing gelatin or derivative
Publication date: 2011-03-24
Patent application number: 20110071227


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Inventors list Agents list Assignees list List by place

Classification tree browser Top 100 Inventors Top 100 Agents Top 100 Assignees

Usenet FAQ Index Documents Other FAQs

Patent application title: RAPIDLY WETTING MATERIAL CONTAINING HYDROCOLLOID, METHOD FOR THE MANUFACTURE THEREOF AND USE THEREOF

Inventors: Michael Ahlers Klaus Flechsenhar Steffen Oesser Michael Grzinia
Agents:
Assignees:
Origin: ,
IPC8 Class: AA61K4742FI
USPC Class:
Publication date: 03/24/2011
Patent application number: 20110071227

Abstract:

The present invention relates to a method for the production of a quickly wettable material containing natural hydrocolloid in the form of a shaped body, in which a material containing natural hydrocolloid in the form of a shaped body is exposed to a plasma.

Claims:

1. A method for the production of a quickly wettable material containing natural hydrocolloid in the form of a shaped body, comprising exposing a material containing natural hydrocolloid in the form of a shaped body to a plasma.

2. The method according to claim 1, wherein the hydrocolloid is selected from the group comprising collagen, gelatin, casein, whey protein, hyaluronic acid, starch, cellulose, pectins, carrageens, chitosan, agar, alginates, hydrolysates thereof, derivatives thereof as well as mixtures with one another.

3. The method according to claim 1, wherein the material comprises more than approximately 50% by weight of hydrocolloid.

4. The method according to claim 1, wherein the material is composed substantially completely of hydrocolloid.

5. The method according to claim 1, comprising drying the material containing hydrocolloid before exposing it to the plasma.

6. The method according to claim 1, wherein the plasma is a low-pressure plasma.

http://www.patentsencyclopedia.com/app/20110071227

GELITA® MEDICAL
Complete Care! Completely Safe!

Declaration of Conformity

Manufacturer	GELITA MEDICAL GmbH Uferstrasse 7 69412 Eberbach Germany
Product	Hemostatic, Surgical, brandname: GELITA-SPON® Absorbable Gelatin Hemostat GELITA-SPON® RAPID³ Absorbable Gelatin Hemostat GELITA-SPON® POWDER Absorbable Gelatin Hemostat GELITA® ENT Absorbable Gelatin Hemostat GELITA TUFT-IT® Absorbable Gelatin Hemostat Sterile non-active non-woven porcine gelatin implants and wound dressings
UMDNS Code GMDN Code	16791 48170
Product Code(s)	See addendum product list for details
Applicable Directives and Standards	Medical Device Directive: Council Directive 93/42/EEC of 14 June 1993 concerning medical devices All other relevant Harmonized Standards as published in the Official Journal of the European Communities are applicable to this type of product.
Classification Conformity Assessment	MDD Annex IX, Class III, Rule 8 and 17 MDD Annex II, section 3 and 4
Notified Body details	DEKRA, Certification B.V. Meander 1051 6825 MJ ARNHEM The Netherlands Notified Body Number: 0344
Certificates	CE MARKING OF CONFORMITY MEDICAL DEVICES Number: 2141242CE01 Validity: 1st December 2018 EC DESIGN EXAMINATION MEDICAL DEVICES Number: 2141242DE01 Validity: 1st December 2018
Date CE mark first affixed	9th of February 2011
Current Validity	1st of December 2018

CARDIOMED INDIA LIMITED 108, 28-29, LINK ROAD, R.G. MARG, LAJPAT NAGAR-IV, NEW DELHI-110024

We, GELITA MEDICAL GmbH, herewith declare that all above mentioned products meet the provisions of the MEDICAL DEVICE DIRECTIVE 93/42 EEC and applicable standards. All supporting documentations are retained under the premises of the manufacturer and the notified body.

Place / Date	Eberbach, 19th December, 2017
Signature / Stamp	GELITA® MEDICAL GELITA MEDICAL GmbH Uferstraße 7 69412 Eberbach Germany Tel.: +49 6271 84-01 Fax: +49 6271 84-2700
Name Position	Laura Hautmanns Managing Director

ADDENDUM

Belonging to certificate: 2141242CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Sterile non-active non-woven porcine gelatin implants and wound dressings.

Issued to:

GELITA MEDICAL GmbH
Uferstrasse 7
69412 Eberbach
Germany

This certificate covers the following product(s):

Addendum 1: Class III, GELITA Absorbable Gelatin Hemostat:

- GELITA-SPON® STANDARD
- GELITA-SPON® RAPID^3
- GELITA-SPON® POWDER
- GELITA-SPON® X-BLOD
- GELITA-SPON® RAPID^3 HD ENT
- GELITA TUFT-IT®

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

CARDIOMED INDIA LIMITED
108, 28-29, LINK ROAD, N.G. MARG, LAJPAT NAGAR-III
NEW DELHI-110024

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DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085398

EC DESIGN-EXAMINATION CERTIFICATE

Number: 2141242DE01

Directive 93/42/EEC on Medical devices, Annex II (4)
(Devices in Class III)

Manufacturer:
GELITA MEDICAL GmbH
Uferstrasse 7
69412 Eberbach
Germany

For the product

Nonactive implants: Absorbable Gelatin Sponge and Non-Woven Hemostat

Documents, that form the basis of this certificate:

Certification Notice 2141242CN, initially dated 9 February 2011
CE Marking of Conformity 2141242CE01
Addendum, initially dated 20 November 2015

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, based on an examination in accordance with Annex II (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex II (4) of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance.
The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 December 2023
Issued for the first time: 9 February 2011
Reissued: 1 December 2018

DEKRA Certification B.V.

Managing Director

J.A. van Vugt
Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

Central Drugs Standard Control Organisation

Directorate General of Health Services

Ministry of Health & Family Welfare
(Medical Device and Diagnostic Division)

FDA Bhawan, Kotla Road
New Delhi-110002
Phone No-011-23236965
Fax: 23236973

File No. : IMP/Form8/MD/2017/15806

Date: 29-12-2017

To,

M/s Cardiomed India Ltd.,
Office No.-108
Ist Floor, Property No-29, Firoj Gandhi Link Road
Lajpat Nagar III, Delhi (India) - 110024

Sub: Import Licence under the Drugs & Cosmetics Act 1940,and Rules 1945 thereunder - regarding.

Sir,

With reference to your application for import licence forwarded to this office, I enclosed licence(s) No. **IL/MD-000803 - RC/MD-000261** dated **29-12-2017**. This/These licence(s) has/have been issued under the Drugs & Cosmetics Act, 1940 and Rules 1945 thereunder.

1. I am to point out that the provisions of Drugs & Cosmetics Act 1940 and Rules 1945 are in addition to and not derogation of any other law for the time being in force and as such the licence(s) issued under Drugs & Cosmetics Act and Rules will be in addition to and distinct from any licence(s) which may be necessary under the Import Trade Control Regulations made of the Government Of India, Ministry of Commerce.
2. The import licence(s) mentioned in para(I) above will not accordingly to itself/themselves be sufficient authority for import of Devices covered by that/those licence(s) if under the Import Trade Control Regulations of the Commerce Ministry separate licence(s) are required for import of such device(s).
3. I am therefore, to advise you to obtain, where necessary licence(s) for import of devices in question under the Import Trade Control Regulations.
4. Any literature or packing accompanying the device or any matter stated on the label should not contravene the provisions of the Drugs and Magic Remedies (Objectionable Advertisement) Act.
5. The Assistant Drugs Controller (India) and Technical Officer of the Central Drugs Control Organization at the ports will be Officers Authorized to inspect the premises of importers establishments for the purpose of Rule 26 of the Drugs & Cosmetics Act and Rules thereunder.
6. Please acknowledge receipt of this letter and its enclosures.

INDIA LIMITED
108, 28-29,
LINK ROAD,
F.G. MARG,
LAJPAT
NAGAR-III

Yours Faithfully

PROFORMA INVOICE

CARDIOMED INDIA LTD.

108, 28-29, Link Road, Feroze Gandhi Marg,
Lajpat Nagar III, New Delhi-110 024
Tel, : +91-11-29838549, 29840210
Email: customersupport@cardiomedindia.com

To:
THE CHIEF
CNC
AIIMS,
ANSARI NAGAR, NEW DELHI-

Date : 12th Oct.2018
Proforma Invoice No. : 930
Challan No. :
Order No. :
Order Date :
Payment :
Dispatch :

Customers Tax Details

S.No.	Description	Rate (Rs.)	Qty	HSN	Amount (Rs.)
1	GR-005 Gelita-Spon Rapid 80x25x4mm	1500	1	30059090	1,500.00
2	GR-007 Gelita Spon Rapid 80x15x7mm	2100	1	30059090	2,100.00
3	GR-010 Gelita Spon Rapid 80x50x4mm	1600	1	30059090	1,600.00
4	GR-310 Gelita Spon Rapid 10x10x4mm	300	1	30059090	300.00
5	GR-610 Gelita Spon Rapid 125x80x4mm	3000	1	30059090	3,000.00

Terms and Conditions

1.GST Extra as applicable
2.Delivery : Within 30 days
3.Price FOR New Delhi

GST as Applicable @5 %

Total -

Rs. Six Thousand Two Hundred Fifty Eight Only

GST NO. 07AAABCC6082A2Z2
PAN NO. AABCC6082A

Drug Licence No. 14/(333)/Dtd.27/04/2009

E.& O.E

Receiver's Signature

For CARDIOMED INDIA LTD.

Authorised Signatory