

Certificate US13/82771

The management system of

NeedleTech Products, Inc.

452 John L. Dietsch Boulevard,
No. Attleboro, MA, 02763, United States



has been assessed and certified as meeting the requirements of

ISO 13485:2003 EN ISO 13485:2012

For the following activities

Design, Development and production of Sterile and Non-sterile Needle Products.

This certificate is valid from 3 September 2015 until 30 April 2018
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 30 April 2018
Issue 5. Certified since 2 May 2012

Authorised by

SGS United Kingdom Ltd Systems & Services Certification
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
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SGS 13485-2 1114

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Mr. David Derrick
Galt Medical Corp. / Theragenics Costa Rica, LTDA
2220 Merritt Drive
Garland, TX, 75041

WW/MW 213391
9 November 2015

Dear Mr. Derrick:

Following the recent re-appraisal of your Company's Management System, I am pleased to inform you that the System in operation conforms to the requirements of ISO 13485:2003, CMDCAS, and MDD 93/42/EEC Annex II (excluding section 4).

Enclosed is a copy of your Certificate. Duplicate copies of these can be purchased by contacting me.

Yours sincerely,

A handwritten signature in black ink that reads 'Laura Prioli'.

Laura Prioli
Health Care/Medical Device Specialist
laura.prioli@sgs.com

The management system of

Galt Medical Corp.

2220 Merritt Drive,
Garland, TX, 75041, United States

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 9 November 2015 until 7 November 2020
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 22 August 2018

Issue 7. Certified since 7 November 2006

Certification is based on reports numbered WW/MW 213391

This is a multi-site certification.

Additional site details are listed on the subsequent page.

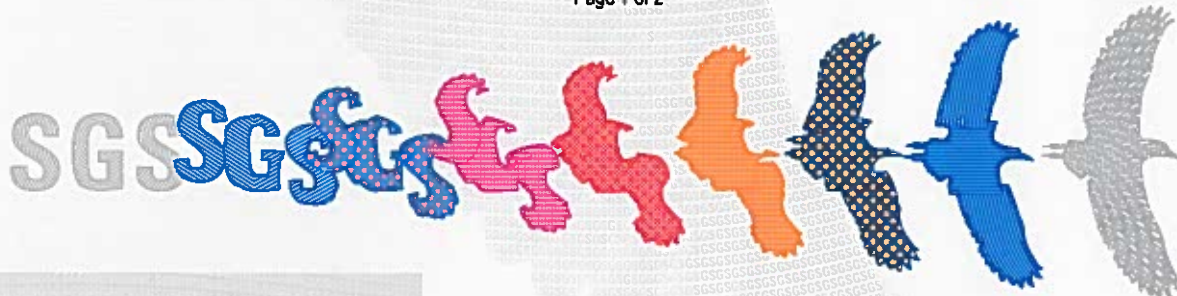
Authorised by

SGS United Kingdom Ltd, Notified Body 0120

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Galt Medical Corp.

Directive 93/42/EEC on medical devices, Annex II (excluding section 4)

Issue 7

Detailed scope

Sterile and non-sterile guidewires, introducers, introducer needles, dilators and sterile kits for cardiovascular and other percutaneous procedures.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market

Additional facilities

Multitenant #5 Calle 4, Zona Franca Coyol, 100 metros al sur de Riteve, El Coyol, Alajuela, Costa Rica

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Certificate US06/3947

The management system of

Galt Medical Corp.

2220 Merritt Drive,
Garland, TX, 75041, United States

has been assessed and certified as meeting the requirements of

ISO 13485:2003

For the following activities

Design, manufacture and distribution of sterile and non-sterile guidewires, introducers, introducer needles, catheters, dilators and sterile kits for cardiovascular and other percutaneous procedures.

Effective Date 10 November 2015 Expiry Date 10 November 2018

Re certification audit due before 22 August 2018

Valid subject to satisfactory surveillance audits.

Issue 9. Certified since 10 November 2006

This is a multi-site certification.

Additional site details are listed on the subsequent page.

Authorised by

Jan Saunders – Business Manager

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CMDCAS recognised registrar

SGS 13485 CMDCAS 0911 MS M2

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Galt Medical Corp.

ISO 13485:2003



Issue 9

Additional facilities

**Multitenant #5 Calle 4, Zona Franca Coyoil, 100 metros al sur de Riteve,
El Coyoil, Alajuela, Costa Rica**

**Scope: Manufacture and distribution of non-sterile introducers,
catheters, dilators for cardiovascular and other percutaneous
procedures.**



Certificate US06/70274.00

The management system of

Galt Medical Corp. / Theragenics Costa Rica, LTDA

2220 Merritt Drive,
Garland, TX, 75041, United States

has been assessed and certified as meeting the requirements of



ISO 13485:2003 EN ISO 13485:2012

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 9 November 2015 until 7 November 2018
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 22 August 2018
Issue 7. Certified since 7 November 2006

Multiple certificates have been issued for this scope

The main certificate is numbered US06/70274.00

This is a multi-site certification.

Additional site details are listed on the subsequent page.

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Galt Medical Corp. / Theragenics Costa Rica, LTDA

ISO 13485:2003 EN ISO 13485:2012



Issue 7

Detailed scope

Design, manufacture and distribution of sterile and non-sterile guidewires, introducers, introducer needles, catheters, dilators, and sterile kits for cardiovascular and other percutaneous procedures. Manufacture of non-sterile sub-assemblies for introducers and dilators.

Additional facilities

Multitenant #5 Calle 4, Zona Franca Coyol, 100 metros al sur de Riteve, El Coyol, Alajuela, Costa Rica

Scope: Manufacture of non-sterile sub-assemblies for introducers and dilators.

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Certificate US06/70274.01

The management system of

Galt Medical Corp.

Multitenant # 5 Calle 4 Zona Franca Coyol 100 metros al sur de Riteve
El Coyol, Alajuela, Costa Rica

has been assessed and certified as meeting the requirements of

ISO 13485:2003 EN ISO 13485:2012

For the following activities

Design, manufacture and distribution of sterile and non-sterile guidewires, introducers, introducer needles, catheters, dilators, and sterile kits for cardiovascular and other percutaneous procedures. Manufacture of non-sterile sub-assemblies for introducers and dilators.

This certificate is valid from 9 November 2015 until 7 November 2018 and remains valid subject to satisfactory surveillance audits.

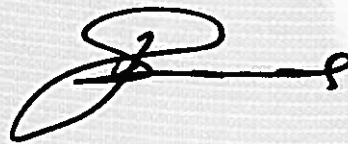
Re certification audit due before 22 August 2018

Issue 7. Certified since 7 November 2006

Multiple certificates have been issued for this scope

The main certificate is numbered US06/70274.00

Authorised by



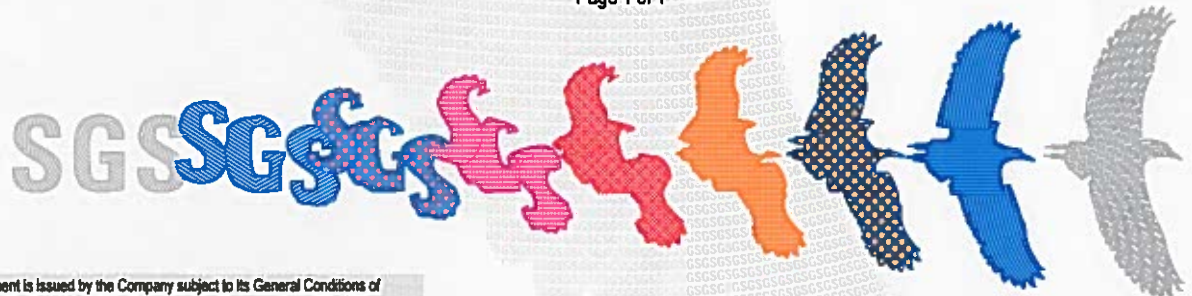
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The management system of

Theragenics Costa Rica, LTDA

Multitenant # 5 Calle 4 Zona Franca Coyoil 100 metros al sur de Riteve
El Coyoil, Alajuela, Costa Rica

has been assessed and certified as meeting the requirements of

ISO 13485:2003 EN ISO 13485:2012

For the following activities

**Design, manufacture and distribution of sterile and non-sterile guidewires, introducers, introducer needles, catheters, dilators, and sterile kits for cardiovascular and other percutaneous procedures.
Manufacture of non-sterile sub-assemblies for introducers and dilators.**

This certificate is valid from 9 November 2015 until 7 November 2018
and remains valid subject to satisfactory surveillance audits.

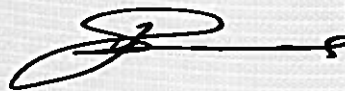
Re certification audit due before 22 August 2018

Issue 7. Certified since 7 November 2006

Multiple certificates have been issued for this scope

The main certificate is numbered US06/70274.00

Authorised by



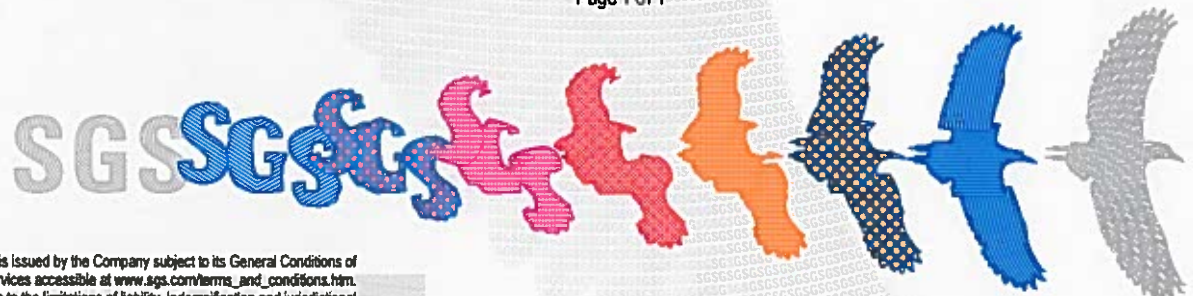
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