

SGS

Certificate US06/70274.00

The management system of

Galt Medical Corp. also trading as Theragenics Costa Rica, LTDA

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

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities

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

This certificate is valid from 30 January 2019 until 07 November 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 22 August 2021
Issue 8. Certified since 07 November 2006

Expiry date of last certificate: 07 November 2018
End date of last recertification audit: 13 September 2018

Multiple certificates have been issued for this scope
The main certificate is numbered US06/70247.00

This is a multi-site certification.
Additional site details are listed on subsequent pages.

Authorised by



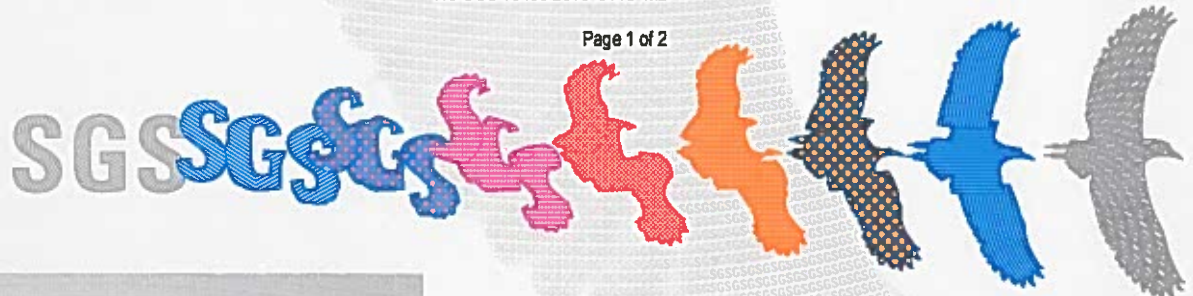
SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118 M2

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Galt Medical Corp. also trading as Theragenics Costa Rica, LTDA

ISO 13485:2016 EN ISO 13485:2016



Issue 8

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



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Certificate US06/70274.01

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Galt Medical Corp. also trading as Theragenics Costa Rica, LTDA

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

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

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.**

This certificate is valid from 30 January 2019 until 07 November 2021
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 22 August 2021

Issue 8. Certified since 07 November 2006

Expiry date of last certificate: 07 November 2018

End date of last recertification audit: 13 September 2018

Multiple certificates have been issued for this scope
The main certificate is numbered US/0670274.00

Authorised by



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Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
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Certificate US06/70274.02

The management system of

Galt Medical Corp. also trading as Theragenics Costa Rica, LTDA

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 13485:2016 EN ISO 13485:2016

For the following activities

**Manufacture of non-sterile sub-assemblies for introducers
and dilators for cardiovascular and other percutaneous procedures**

This certificate is valid from 30 January 2019 until 07 November 2021
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 22 August 2021
Issue 8. Certified since 07 November 2006

Expiry date of last certificate: 07 November 2018
End date of last recertification audit: 13 September 2018

Multiple certificates have been issued for this scope
The main certificate is numbered US06/70247.00

Authorised by



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