



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 02 August 2021 until 07 November 2024
and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date.
Issue 10. Certified since 07 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.



Authorised by



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21HC 13485 2016 0421 M2

Page 1 of 2



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

ISO 13485:2016 EN ISO 13485:2016



Issue 10

Detailed scope

Design, manufacture and distribution of sterile and non-sterile guidewires, introducers, introducer needles, catheters, dilators, Hemostasis Valves and sterile, non-sterile kits for cardiovascular and other percutaneous procedures. Manufacture of non-sterile subassemblies for introducers and dilators. Distribution of the guidewire manipulators.

Additional facilities

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



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Certificate US06/70274.01

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

Design, manufacture and distribution of sterile and non-sterile guidewires, introducers, introducer needles, catheters, dilators, Hemostasis Valves and sterile, non-sterile kits for cardiovascular and other percutaneous procedures. Distribution of the guidewire manipulators.

This certificate is valid from 02 August 2021 until 07 November 2024 and remains valid subject to satisfactory surveillance audits. Recertification audit due a minimum of 60 days before the expiration date Issue 10, Certified since 07 November 2006

Multiple certificates have been issued for this scope The main certificate is numbered US06/70274.00 The validity of this certificate depends on the validity of the main certificate.



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The management system of

Galt Medical Corp. also trading as 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 13485:2016 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 07 November 2021 until 07 November 2024
and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date
Issue 9. Certified since 07 November 2006

Multiple certificates have been issued for this scope
The main certificate is numbered US06/70274.00
The validity of this certificate depends on the validity of the main certificate.

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21HC 13485 2016 0421

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Certificate Number US19/819943298
The management system of

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

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

Facility identification number : F002875

has been audited against the criteria stated below and found to conform to those criteria for the scope contained in this certificate



MDSAP (ISO 13485:2016)

Australia:
Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure [including design]

Brazil:
RDC ANVISA n. 16/2013 / RDC ANVISA n. 23/2012 /RDC ANVISA n. 67/2009

Canada:
Medical Devices Regulations – Part 1 SOR 98/282

United States:
21 CFR 820 / 21 CFR 803 / 21 CFR 806 / 21 CFR 807 – Subparts A to D

For the following activities and devices

See second page for the scope.

The certificate is valid from

Effective Date: 2021-11-08 until Expiry Date: 2024-11-07

and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 2024-09-14

Issue 2. Certified since 2019-08-05

Authorised by L Henderson
Business Manager



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MDSAP M2

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Certificate Number US19/819943298, continued

The management system of

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

MDSAP (ISO 13485:2016)



Issue 2

Detailed scope

**Design, manufacture and distribution of sterile and non-sterile
guide-wires, introducers, introducer needles,
catheters, dilators and sterile kits for cardiovascular
and other percutaneous procedures.
Distribution of the guidewire manipulators.**

Additional facilities

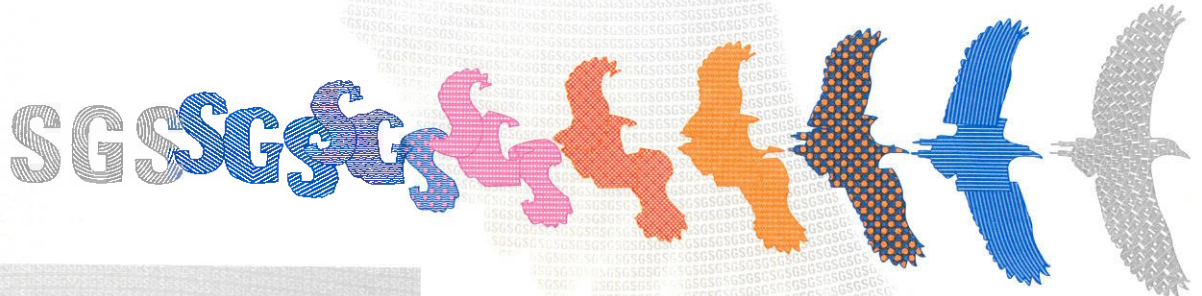
**Theragenics Costa Rica, LTDA
Multitenant #5 Calle 4, Zona Franca Coyoil, 100 metros al sur de Riteve,
El Coyoil, Alajuela, Costa Rica**

Dun & Bradstreet D-U-N-S identification number : F002874



Site specific scope:

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



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