

Certificate US06/70274.00

The management system of

# Galt Medical Corp.

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

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, drainage 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.

This certificate is valid from 22 October 2024 until 22 October 2027 and remains valid subject to satisfactory surveillance audits.

Issue 12. Certified since 07 November 2006

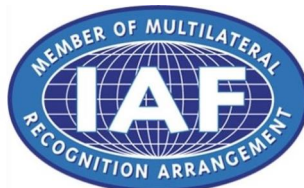
Certified activities performed by additional sites are listed on subsequent pages.

*L. Moran*

Authorised by

Liz Moran  
Business Manager

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



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Certificate US06/70274.00, continued

# Galt Medical Corp.

# SGS

**ISO 13485:2016**  
**EN ISO 13485:2016**

Issue 12

## Sites

Galt Medical Corp.  
2220 Merritt Drive, Garland, TX, 75041, United States Of America

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.

Theragenics Costa Rica, LTDA.  
Building 13.3 Calle 4, Zona Franca Coyoil, El Coyoil, Alajuela, 11005, Costa Rica

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



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