

Certificate US19/819943298

The quality management system of

# Galt Medical Corp.

SGS

2220 Merritt Drive, Garland, TX, 75041, United States Of America  
Facility number: F002875

has been assessed and certified as meeting the requirements of

## MDSAP (ISO 13485:2016)

Australia: Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full Quality Assurance System

Brazil: RDC ANVISA n. 665/2022 - Good Manufacturing Practices; RDC ANVISA n. 551/2021 – Field Actions; RDC ANVISA n. 67/2009 - Vigilance

Canada: Medical Devices Regulations (SOR/98-282) Part 1 - General

USA: 21 CFR Part 803 - Medical Device Reporting; 21 CFR Part 806 - Reports of Corrections and Removals; 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing, 21 CFR Part 820 - Quality System Regulation

For the following activities

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

Distribution of the guidewire manipulators for cardiovascular and other percutaneous procedures.

This certificate is valid from Effective date 2025-08-28 until Expiry date 2027-10-22 and remains valid subject to satisfactory surveillance audits.

Issue 5. Certified since 2019-08-05

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

*L. Henderson*

Authorised by

Lynn Henderson

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SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at [www.SGS.com](http://www.SGS.com).



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## MDSAP (ISO 13485:2016)

Issue 5

### Sites

Galt Medical Corp.  
2220 Merritt Drive, Garland, TX, 75041, United States of America  
Facility number: F002875

Design, manufacture, contract manufacture of sterile and non-sterile guidewires, introducers, introducer needles, drainage catheters, dilators, hemostasis valves and introducer kits. Distribution of the guidewire manipulators.

Theragenics Costa Rica, LTDA.  
Building 13.3 Calle 4, Zona Franca Coyol, El Coyol, Alajuela, 11005, Costa Rica  
Facility number: F002874

Manufacture of non-sterile components for guidewires, introducers, introducer needles, drainage catheters, dilators, hemostasis valves and introducer kits.

Campus:  
Building B28, Module B, Zone Franca Coyol, Alajuela, Costa Rica



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