

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

University of Utah
Center for Medical Innovation
10 North 1900 East
Room 24
Salt Lake City
Utah
84112
USA

Holds Certificate No:

FM 650953

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design, development, and evaluation of Medical Devices, including Diagnostic Devices, Therapeutic Devices, Hematology and Pathology Devices, Immunology and Microbiology Devices, Anesthesiology Devices, Cardiovascular Devices, Dental Devices, Ear, Nose, and Throat Devices, Gastroenterology-Urology Devices, General and Plastic Surgery Devices, General Hospital and Personal Use Devices, Neurological Devices, Obstetrical and Gynecological Devices, Ophthalmic Devices, Orthopedic Devices, Physical Medicine Devices, and Radiology Devices.

For and on behalf of BSI:



Carlos Pitanga, SVP, System Certification and Compliance

Original Registration Date: 2017-06-30

Latest Revision Date: 2017-06-30

Effective Date: 2017-06-30

Expiry Date: 2020-06-29

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