

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Quality Electrodynamics, LLC.
6655 Beta Drive Suite 100
Mayfield Village
Ohio
44143
USA

Facility ID Number: F000368

Holds Certificate No:

MDSAP 683565

Statement of Conformity: The company listed on this certificate has been audited and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design, development, manufacture, distribution, and service of Magnetic Resonance Imaging RF coils for use with MRI systems.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-04-29

Effective Date: 2022-03-03

Expiry Date: 2025-03-02



BSI Group America Inc. is an MDSAP authorized auditing organization

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