

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**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

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 MO No 169 (2004), as amended by MHLW MO No 60 (2021), 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, Magnetic Resonance Elastography (MRE) devices, and related software for use with MRI systems.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2019-04-29

Effective Date: 2025-03-03

Expiry Date: 2028-03-02



BSI Group America Inc. is an MDSAP recognised auditing organization

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