

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Analog Devices, Inc.
1 Analog Way
Wilmington
Massachusetts
01887
USA

Holds Certificate Number:

MD 803146

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

The design, development, manufacture, and distribution of active, non-implantable devices for the monitoring of physiological parameters including cardiac, respiratory and renal functions and processes.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2024-05-14

Latest Revision Date: 2024-05-14

Effective Date: 2024-05-14

Expiry Date: 2027-04-24



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Analog Devices, Inc.
1 Analog Way
Wilmington
Massachusetts
01887
USA

Facility ID Number: F007246

Holds Certificate No:

MDSAP 803145

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

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

The design, development, manufacture, and distribution of active, non-implantable devices for the monitoring of physiological parameters including cardiac, respiratory and renal functions and processes.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2024-04-25

Effective Date: 2024-04-25

Expiry Date: 2027-04-24



BSI Group America Inc. is an MDSAP recognized auditing organization