

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Artivion, Inc.
1655 Roberts Boulevard NW
Kennesaw
Georgia
30144-3632
USA

Facility ID Number: F006454

Holds Certificate No:

MDSAP 781305

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

Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

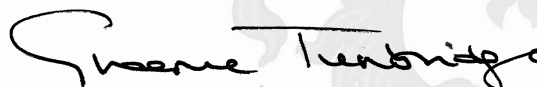
Canada: Medical Devices Regulations - Part 1 - SOR 98/282

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, 21 CFR 821

Please see scope page.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2023-10-08

Effective Date: 2023-10-08

Expiry Date: 2026-08-23



BSI Group America Inc. is an MDSAP recognised auditing organization

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Certificate No: **MDSAP 781305**

Registered Scope:

Design and development, production, and distribution of mechanical heart valves, aortovalvular prosthesis, sutures and surgical instruments, vascular implants and catheters, aortic stent grafts, cardiovascular bovine pericardial patches, surgical adhesives and accessories. Contract manufacturing of hemostatic agents and pyrolytic carbon-coated medical device components.



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This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](https://www.bsigroup.com/ClientDirectory). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.

Certificate No: **MDSAP 781305**

Location	Registered Activities
Artivion, Inc. 1655 Roberts Boulevard NW Kennesaw Georgia 30144-3632 USA Facility ID Number: F006454	Design and development, manufacturing, distribution, and storage of medical devices for the treatment of cardiovascular and vascular diseases, laboratories for quality control and microbiology, contract manufacturing services, servicing of surgical laser equipment, and processing and distribution of human tissue.
Artivion, Inc. 2140 Barrett Park Drive Suite 109 Kennesaw Georgia 30144-3632 USA Facility ID Number: F006454	Warehouse, storage of raw materials.



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