



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Wells Johnson Company 8000 South Kolb Rd Tucson Arizona 85756 USA

Facility ID Number: F007501

Holds Certificate No:

MDSAP 810111

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

> Design, development, manufacture and distribution of infusers, surgical cannulas, cannisters, liners and sterile tubing. Design, development, manufacture, servicing and distribution of infiltration pumps and aspirators.

For and on behalf of BSI:

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Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2025-06-11

Effective Date: 2025-06-11

Expiry Date: 2026-03-12

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This certificate remains the property of BSI and shall be returned immediately upon request. An electronic certificate can be authenticated <u>online</u>. 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.