

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Medical Components, Inc.
Also doing business as Medcomp
1499 Delp Drive
Harleysville
Pennsylvania
19438
USA

Facility ID Number: F000286

Holds Certificate No:

MDSAP 691198

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

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-02-19

Effective Date: 2023-09-07

Expiry Date: 2025-09-28



BSI Group America Inc. is an MDSAP recognised auditing organization

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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](http://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.

Certificate No: **MDSAP 691198**

Registered Scope:

Design, Development, Manufacturing, and Distribution of sterile catheter locking solution, dialysis, infusion, and drainage catheters for central and peripheral vascular and cavity access, and their associated repair, replacement, and adjunct accessories used in acute and chronic extracorporeal and maintenance therapies.



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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 691198**

Location	Registered Activities
Medical Components, Inc. Also doing business as Medcomp 1499 Delp Drive Harleysville Pennsylvania 19438 USA Facility ID Number: F000286	Design, Development, Manufacturing, and Distribution of sterile catheter locking solution, dialysis, infusion, and drainage catheters for central and peripheral vascular and cavity access, and their associated repair, replacement, and adjunct accessories used in acute and chronic extracorporeal and maintenance therapies.
Medical Components, Inc 3088 East 33rd Place Yuma Arizona 85365 USA Facility ID Number: F001900	Warehousing, re-labeling, inventory control, shipping and customer service.



Original Registration Date: 2020-02-19 Effective Date: 2023-09-07 Expiry Date: 2025-09-28

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