

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. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009

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

Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act

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

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.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-02-19

Effective Date: 2022-10-13

Expiry Date: 2025-09-28



BSI Group America Inc. is an MDSAP recognised auditing organization

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Location

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1499 Delp Drive
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USA
Facility ID Number: F000286

Registered Activities

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.



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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.