

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Medical Components, Inc.
dba Medcomp
1499 Delp Drive
Harleysville
Pennsylvania
19438
USA

DUNS Number: 03-800-0253

Holds Certificate No:

MDSAP 691198

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - 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, Manufacture, and Distribution of sterile catheter locking solution, sterile and nonsterile ECG-based peripherally inserted central catheter placement and tip location confirmation systems, 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:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-02-19

Effective Date: 2020-02-19

Expiry Date: 2022-09-28



BSI Group America Inc. is an MDSAP authorized auditing organization

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Certificate No: **MDSAP 691198**

Location	Registered Activities
Medical Components, Inc. dba Medcomp 1499 Delp Drive Harleysville Pennsylvania 19438 USA DUNS Number: 03-800-0253	Design, Development, Manufacture, and Distribution of sterile catheter locking solution, sterile and nonsterile ECG-based peripherally inserted central catheter placement and tip location confirmation systems, 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 DUNS Number: 08-075-7988	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.