



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

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

Holds Certificate Number:

MD 636611

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, Development, Manufacturing, 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.

jang Colado

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2015-07-16 Latest Revision Date: 2020-09-28 Effective Date: 2020-09-29 Expiry Date: 2022-09-28

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...making excellence a habit."

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated <u>online</u>. Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK. A Member of the BSI Group of Companies.

Certificate No: MD 636611

Location

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

Medical Components, Inc 3088 East 33rd Place Yuma Arizona 85365 USA **Registered Activities**

Design, Development, Manufacturing, and Distribution of sterile catheter locking solution, sterile and nonsterile ECGbased 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.

Warehousing, re-labeling, inventory control, shipping and customer service.

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