

Certificate of Registration

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

This is to certify that:

Bayer Medical Care Inc.
Also doing business as Medrad, Inc.
1 Bayer Drive
Indianola
Pennsylvania
15051-0780
USA

Holds Certificate Number:

MD 566559

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, manufacture, and distribution of vascular injection systems, sterile disposable syringes, sterile disposable administration sets, MRI endorectal coils, radiation and contrast dose management software, anatomic stabilization devices, infusion pump systems and vital signs monitors.
Installation and service of vascular injection systems, radiation and contrast dose management software, infusion pump systems and vital signs monitors.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2010-09-24

Latest Revision Date: 2017-08-10

Effective Date: 2019-02-21

Expiry Date: 2021-09-12

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Certificate No: **MD 566559**

Location	Registered Activities
Bayer Medical Care Inc. Also doing business as Medrad, Inc. 1 Bayer Drive Indianola Pennsylvania 15051-0780 USA	Design and development of vascular injection systems, sterile disposable syringes, sterile disposable administration sets, MRI endorectal coils, radiation and contrast dose management software<(>,<)> anatomic stabilization devices, infusion pump systems and vital signs monitors. Manufacture of sterile disposable syringes, sterile disposable administration sets, and anatomic stabilization devices. Purchasing, customer service, complaints, CAPA, and internal audits.
Bayer Medical Care Inc. 625 Alpha Drive Pittsburgh Pennsylvania 15238 USA	Manufacture, distribution, installation, and service of vascular injection systems, radiation and contrast dose management software, infusion pump systems, and vital signs monitors. Manufacture and distribution of MRI endorectal coils and anatomic stabilization devices.
Bayer Medical Care Inc. 150 Victory Road Saxonburg Pennsylvania 16056 USA	Manufacture of disposable syringes, and disposable administration sets.

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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 [online](#).

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
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