



By Royal Charter

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, radiation and contrast dose management software, radiology imaging review software, and infusion pump systems. Installation and service of vascular injection systems, radiation and contrast dose management software, radiology imaging review software, and infusion pump systems.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2010-09-24

Latest Revision Date: 2024-08-23

Effective Date: 2024-09-13

Expiry Date: 2027-09-12



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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
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 566559

Location	Registered Activities
Bayer Medical Care Inc. Also doing business as Medrad, Inc. 1 Bayer Drive Indianola Pennsylvania 15051-0780 USA	Design, development, manufacture and distribution of vascular injection systems, sterile disposable syringes, sterile disposable administration sets, radiation and contrast dose management software, radiology imaging review software, and infusion pump systems. Installation and service of vascular injection systems, radiation and contrast dose management software, radiology imaging review software, and infusion pump systems.
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, and infusion pump systems.
Bayer Medical Care Inc. 150 Victory Road Saxonburg Pennsylvania 16056 USA	Manufacture of disposable syringes, and disposable administration sets.
Bayer Medical Inc. 1100 South Noah Drive Saxonburg Pennsylvania 16056 USA	Incoming inspection and storage of components for use in the manufacture of sterile disposable syringes and sterile disposable administration sets. Incoming inspection and testing of externally manufactured sterile disposable syringes and sterile disposable administration sets.

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