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By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 729753 R000

Manufacturer: Bayer Medical Care Inc.

Address:
1 Bayer Drive
Indianola
Pennsylvania
15051-0780
USA

Single Registration Number: US-MF-000007050

EU Authorised Representative: Bayer Medical Care B.V.

Address:
Avenue Ceramique 27
6221 KV Maastricht
The Netherlands

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2021-12-10**

Current Issue Date: **2023-02-08**

Starting Validity Date: **2023-02-08**

Expiry Date: **2026-12-09**

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Device Schedule: Class III and Class IIb devices

Class IIb under Rule 12	Intended purpose
PET Infusion Systems	The PET infusion system is intended to be used specifically for the purposes of venous injections of radiopharmaceuticals and common flushing solutions into patients during molecular imaging procedures. The PET infusion system is also intended to provide effective radiation shielding to medical personnel from radiation exposure during nuclear medicine diagnostic procedures. Do NOT attempt to use the infusion system for any other purpose.
MR Injection Systems	The injector is intended to be used specifically for the purposes of venous injections of contrast agents and common flushing solutions into patients during MR imaging procedures. Do NOT attempt to use the injector for any other purpose.
CV Injection Systems	The cardiovascular injection system is intended to be used specifically for the purpose of injecting contrast medium and common flushing solutions into patients during angiographic studies. Do NOT attempt to use the injector for any other purpose.
CT Injection Systems	The injector is intended to be used specifically for the purposes of venous injections of contrast agents and common flushing solutions into patients during CT imaging procedures. Do NOT attempt to use the injector for any other purpose.
Hand controller accessories for Injector Systems	The hand controller accessories are specifically used with their corresponding injector systems in the x-ray angiography environment.
Image System Interface (ISI) Accessories	The ISI Module is indicated for the specific purpose of allowing an injector to interface with an imaging scanner.

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Sterile Disposables and Syringes	Class IIa
Sterile Controller Sheaths	Class Is
Imaging Viewer software	Class Im

For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.
For Class Im devices, the Notified Body conformity assessment is limited to the aspects relating to the conformity of the devices with the metrological requirements.

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2021-12-10	3217785	Issued
2022-07-04	3635012	Supplemented - Addition of Class IIb Rule 12 devices •MEDRAD® Stellant CT Injection System with Certegra Workstation •MEDRAD® Stellant FLEX CT Injection System with Certegra Workstation •MEDRAD® Stellant Image System Interface (ISI) accessory - Addition of Class Im software •Calantic Viewer
Current	3640845	Supplemented - Addition of MEDRAD® Mark 7 Arterion Injection System, MEDRAD® MRXperion MR Injection System and MEDRAD® Image System Interface (ISI2) accessories Amended - Change device table generalisation of device groups which previously listed specific device names Amended - Removal of subcontractors listed on certificate Amended - New sterilization subcontractor has been added Amended - Change of address for a manufacture subcontractor

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