EC DECLARATION OF CONFORMITY

We: **With Our:**

Manufacturer	EC Authorized Representative
Bayer Medical Care, Inc. 1 Bayer Drive Indianola, PA 15051 USA	Bayer Medical Care, B.V. Avenue Céramique 27 6221 KV Maastricht The Netherlands
Manufacturer Single Registration Number (SRN): Bayer Medical Care, Inc.: US-MF-000007050	EC Authorized Rep Single Registration Number (SRN): NL-AR-000000240

PRODUCT/PRODUCT FAMILY LIST INFORMATION

Catalog No.	Product	Risk Classification	Basic UDI-DI
SCT-310	MEDRAD Stellant CT Injection System with Certegra Workstation	Class IIb, Rule 12	(8013)0616258TFCN-0082IIbZ3
Connect.CT	Connect.CT Application	Class IIb, Rule 12	(8013)0616258TFCN-0082IIbZ3
MIS P3TC	Personalized Patient Protocol Technology (P3T) P3T Cardiac Module for Certegra Workstation	Class IIb, Rule 12	(8013)0616258TFCN-0082IIbZ3
MIS P3TA	Personalized Patient Protocol Technology (P3T) P3T Abdomen Module for Certegra Workstation	Class IIb, Rule 12	(8013)0616258TFCN-0082IIbZ3
MIS P3TPA	Personalized Patient Protocol Technology (P3T) P3T Pulmonary Angiography (PA) for Certegra Workstation	Class IIb, Rule 12	(8013)0616258TFCN-0082IIbZ3

PRODUCT INTENDED USE:

The MEDRAD® Stellant CT Injection System with Certegra® Workstation is indicated for the specific purpose of injecting intravenous contrast media or saline into humans for diagnostic studies in computed tomography (CT) applications.

Connect.CT Application is indicated for the specific purpose of allowing an injector to interface with a CT scanner.

Personalized Patient Protocol Technology (P3T) P3T Cardiac Module for Certegra Workstation is indicated for use in CT angiography of cardiac structures, including coronary arteries, chambers of the heart, and thoracic and abdominal aorta.

Personalized Patient Protocol Technology (P3T) P3T Abdomen Module for Certegra Workstation is indicated for use with CT imaging of abdominal organs (i.e., liver, pancreas, kidneys).

Personalized Patient Protocol Technology (P3T) P3T Pulmonary Angiography (PA) for Certegra Workstation is indicated for use in CT angiography of cardiac structures, including coronary arteries, chambers of the heart, pulmonary vasculature, thoracic and abdominal aorta.

DECLARATION:

Bayer Medical Care, Inc. with sole responsibility declares that the above mentioned products meet all applicable requirements of the:

- European Union Medical Device Regulation (2017/745)
- Machinery Directive (2006/42/EC)

The above mentioned products:

- do not incorporate, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 (2) of Directive 2001/83/EC;
- do not incorporate, as an integral part, a substance or a human blood derivative defined in Article 1(10) of 2001/83/EC.; and
- are not manufactured utilizing tissues of animal origin as referred to in Commission Directive 2003/32/EC
- are in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, amended up to and inclusive of Directive (EU) 2017/2012 (RoHS) and (EU 2015/863 (RoHS) and have been demonstrated to meet the requirements specified in Article 4.
- The quality system concerning the above mentioned product types has been evaluated by BSI (2797) utilizing the conformity assessment procedure identified in Annex IX, Chapters I and III of EU 2017/745, and certified on MDR 729753

The CE marking has been affixed on the device according to EU Medical Device Regulation 2017/745.

This certificate is effective for the applicable manufactured products with the Basic UDI-DI listed above as of the signature date below.

Troy Jack
Head of Global Regulatory Affairs Operational Excellence
Indianola, PA USA

12 DECEMBER 2023
Date