EC DECLARATION OF CONFORMITY

We: **With Our:**

Manufacturer	EC Authorized Representative
Bayer Medical Care, Inc. 1 Bayer Drive Indianola, PA 15051-0780 USA	Bayer Medical Care, B.V. Avenue Céramique 27 6221 KV Maastricht The Netherlands
Manufacturer Single Registration Number (SRN): 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
AVA 500 PEDL	MEDRAD® Avanta Fluid Management Injection System	Class IIb, Rule 12	(8013)0616258TFCN-0060Q8
AVA 500 TABL	MEDRAD® Avanta Fluid Management Injection System	Class IIb, Rule 12	(8013)0616258TFCN-0060Q8

PRODUCT INTENDED USE:

The MEDRAD® Avanta Fluid Management Injection System is specifically intended for operation in the X-ray angiography environment. It is designed to administer intravascular radio-opaque contrast compounds and common flushing agents at various volumes and flow rates into humans for use in diagnostic and interventional angiographic procedures performed in cardiology, radiology and vascular surgery.

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.

30 NOVEMBER 2023

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

Date