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 BV Avenue Ceramique 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
MRXP 200	MEDRAD® MRXperion MR Injection System	Class IIb, Rule 12	(8013)0616258TFCN-0089IIb2P

PRODUCT INTENDED USE:

MEDRAD® MRXperion MR Injection System:
The MEDRAD® MRXperion MR Injection System is a syringe-based fluid delivery system indicated for delivery of contrast media and saline during MR applications. It is intended to be used for the specific purpose of injecting intravenous MR contrast media and saline into the human vascular system for diagnostic studies in magnetic resonance imaging (MRI) applications with MRI scanners that have a magnetic field strength between 0.55 and 7.0 Tesla. Only trained healthcare professionals are intended to operate this device.

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) 2017/2102 (RoHS) and (EU) 2015/863 (RoHS) have been demonstrated to meet the requirements specified in Article 4.
- The quality system concerning the above mentioned class IIb product types have been evaluated by BSI (2797) utilizing the conformity assessment procedure identified in Annex IX, Chapter 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.
Bayer Medical Care Inc has changed CE marking from CE 0086 to CE 2797 as of February 15, 2019.

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, Global Regulatory Affairs Operational Excellence
Bayer Medical Care, Inc.
Indianola, PA-15051, USA

27 July 2023
Date: