EC DECLARATION OF CONFORMITY

We:

Bayer Medical Care Inc.
1 Bayer Drive
Indianola, PA 15051-0780 USA

With our Authorized EC Representative:

Bayer Medical Care BV
Horsterweg 24
6199 AC Maastricht Airport
The Netherlands

BAYER MEDICAL CARE INC.
PRODUCT/PRODUCT FAMILY LIST INFORMATION

Catalog No.	Product	Classification	Start of the CE Mark (Cut In Number)
System			
ART 700 PEDL	MEDRAD Mark 7 Arterion Injection System	Class IIb, Rule 11	Serial: 2XXXXX
ART 700 TABL	MEDRAD Mark 7 Arterion Injection System		Serial: 2XXXXX
ART 700 BASC	MEDRAD Mark 7 Arterion Injection System		Serial: 2XXXXX
ART 700 OCS	MEDRAD Mark 7 Arterion Injection System		Serial: 2XXXXX
ART 700 VFL	MEDRAD Mark 7 Arterion Injection System		N/A
Disposables			
VF HC	MEDRAD VFlow Disposable Hand Controller	Class IIb, Rule 11	Batch: Box GTIN: 10616258006991 Package GTIN: 00616258006994

DECLARATION:

Bayer Medical Care Inc. declares that the above mentioned products meet all applicable requirements of the European Council Directive 93/42/EEC (as amended by 2007/47/EC) and 2006/42/EC including:

- Annex II, Clause 3 - EC DECLARATION OF CONFORMITY (Full Quality Assurance System)
- The essential health and safety requirements for Medical Devices in Annex I

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 of Directive 2001/83/EC;
- do not incorporate, as an integral part, a substance or a human blood derivative referred to in section 7.4 of Annex I of Directive 93/42/EEC as amended by 2007/47/EC; and
- are not manufactured utilizing tissues of animal origin as referred to in Commission Directive 2003/32/EC (1)
- are in conformity with Directive EU 2015/863 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 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 a government accredited European third party organization.

The CE marking has been affixed on the device according to article 17 of the EC Directive, 93/42/EEC as amended by 2007/47/EC.

This certificate is effective for the applicable manufactured products beginning with the cut-in numbers listed in the table above.

Effective 15-Feb-2019, Bayer Medical Care Inc. transitioned Notified Bodies from BSI United Kingdom (CE 0086) to BSI Netherlands (CE 2797) as is reflected on CE 543532.

Head, Radiology Regulatory Affairs

13 APRIL 2022
Date