



**EC DECLARATION OF CONFORMITY**

**We:** Bayer Medical Care Inc.  
1 Bayer Drive  
Indianola, PA 15051 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**

PRODUCT NAME	EC CLASS
MRXperion MR Injection System: MRXP 200	IIb, Rule 11

Bayer Medical Care Inc.  
1 Bayer Drive  
Indianola, PA 15051  
U.S.A.

(412) 767-2400

www.ri.bayer.com

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

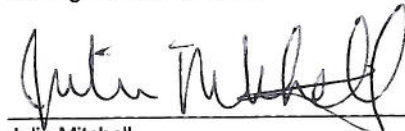
The above mentioned products:

- 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)
- Conforms to RoHs Directive 2011/65/EU


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.

Start of CE marking: This certificate is effective immediately for MRXperion MR Injection Systems starting with S/N 100001.

  
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 Julia Mitchell  
 Head of Commercial Quality – Radiology and Interventional

NOVEMBER 25 2014  
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 Date

  
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 Troy Jack  
 Head, Global Regulatory Affairs, Operational Excellence

NOVEMBER 25, 2014  
 \_\_\_\_\_  
 Date