Bayer HealthCare

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 Syringe Kit: XP 65/115VS	IIa, Rule 2

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, 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)
- 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 System Syringe Kits starting with batch number 300003.

Julia Mitchell
Head of Commercial Quality – Radiology and Interventional

November 25 2014
Date

Troy Jack
Head, Global Regulatory Affairs, Operational Excellence

NOVEMBER 25, 2014
Date