



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)
SSQK 65/115VS	Disposable MRI Kit for 65/115 MR Injector System	Class IIa, Rule 2	Box: 10616258005420 Package: 00616258005423
SSQK 115	Saline Syringe & Tubing for MR Injector System	Class IIa, Rule 2	Box: 10616258005468 Package: 00616258005461
SSIT 96VLD	MEDRAD Spectris Solaris MRI Integral "T" with Check Valve	Class IIa, Rule 2	Box: 10616258005451 Package: 00616258005454
FFA 50	Female – Female Adapter	Class IIa, Rule 2	Box: 10616258005673 Package: 00616258005676

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)

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.



Troy Jack
Head, Radiology Regulatory Affairs
Operational Excellence

20 March 2020
Date