



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, B.V. Avenue Céramique 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
SSQK 65/115VS	Disposable MRI Kit for 65/115 MR Injector System	Class IIa, Rule 2	(8013)0616258TFCN-0048QJ
SSQK 115	Saline Syringe & Tubing for MR Injector System	Class IIa, Rule 2	
SSIT 96VLD	MEDRAD Spectris Solaris MRI Integral "T" with Check Valve	Class IIa, Rule 2	
FFA 50	Female – Female Adapter	Class IIa, Rule 2	

PRODUCT INTENDED USE:

The contents of this package are intended to be used in the delivery of contrast media. These devices are indicated for single-use only with injectors from Bayer.

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)

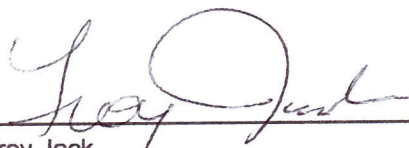
The above mentioned products:

- 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
- The quality system concerning the above mentioned product types has been evaluated by BSI (2797) utilizing the conformity assessment procedure identified in Annex IX, Chapters 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.

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

6 FEBRUARY 2024
Date