Bayer HealthCare

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 CE Mark
SDS MP1	MEDRAD Stellant Multi-Patient Kit	Class IIa, Rule 2	Batch 8401503
SPD 250	MEDRAD Stellant 250cm Single Patient Disposable	Class IIa, Rule 2	Batch 8509760

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) including:

- Annex II, Clause 3 - EC DECLARATION OF CONFORMITY (Full Quality Assurance System)
- The essential health and safety requirement 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 I 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; 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 products beginning with the serial numbers, batch numbers, date codes, or part numbers listed in the table above.

Signature: _____ Date: 24 SEPTEMBER 2015
Name: Troy Jack
Function: Head, Global Regulatory Affairs
Operational Excellence