## 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 (Serial or Batch No.) |
|---|---|---|---|
| INT SYS 200 | MEDRAD Intego | Class IIb, Rule 11 | Serial No. 2XXXXX or 3XXXXX |

**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), Council Directive 2006/42/EC including, and Council Directive 96/29/EURATOM 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 of 93/42/EEC as amended by 2007/47/EC and applicable requirements of 2006/42/EC.
- The applicable sections of 96/29/EURATOM

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)
- Are in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment and have been demonstrated to meet the requirements specified in Article 4.
- Are in conformity with the essential requirements of Directive 2014/53/EU (Intego systems beginning with serial number 3XXXXX only).

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

4 MARCH 2019
Date