Declaration of Conformity

Agfa NV

Septestraat 27, 2640 Mortsel, Belgium

declares that the product

Name:	**CR 12-X**
Model / Version:	**5151/200**
Application:	**General Radiology**

complies with the requirements of the 93/42/EEC Directive (Medical Device) via the Swedish Law Legislation LVFS 2003:11, and that for this Class IIa device the procedures of Annex II have been applied in order to mark the device with the CE-label.

The notified body involved in the above specified procedures is Intertek Semko AB holding the registration number 0413

is in conformity with Directive 2011/65/EU (RoHS) 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.

In case of product changes not accepted in writing by Agfa this declaration will expire.
This declaration is valid maximum for 5 years after the signature date.

Position, Signature & Date

14 -02- 2019

Paul Merckx
Head of Quality Assurance & Regulatory Affairs
Agfa NV

AGFA

Declaration of Conformity

Agfa NV

Septestraat 27, 2640 Mortsel, Belgium

declares that the product

Name:	**CR 15-X**
Model / Version:	**5151/300**
Application:	**General Radiology**

complies with the requirements of the 93/42/EEC Directive (Medical Device) via the Swedish Law Legislation LVFS 2003:11, and that for this Class IIa device the procedures of Annex II have been applied in order to mark the device with the CE-label.

The notified body involved in the above specified procedures is Intertek Semko AB holding the registration number 0413

is in conformity with Directive 2011/65/EU (RoHS) 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.

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Position, Signature & Date

14 -02- 2019

Paul Merckx
Head of Quality Assurance & Regulatory Affairs
Agfa NV

AGFA

Declaration of Conformity

Agfa NV

Septestraat 27, 2640 Mortsel, Belgium

declares that the product

Name: **CR30-Xm**

Model / Version: **5179/100**

Application: **General Radiology / Mammography**

complies with the requirements of the 93/42/EEC Directive (Medical Device) via the Swedish Law Legislation LVFS 2003:11, and that for this Class IIa device the procedures of Annex II have been applied in order to mark the device with the CE-label.

The notified body involved in the above specified procedures is Intertek Semko AB holding the registration number 0413

is in conformity with Directive 2011/65/EU (RoHS) 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.

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Paul Merckx
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