

Declaration of Conformity



AGFA HEALTHCARE N.V.

Septestraat 27, 2640 Mortsel, Belgium

declares that the product

Category: Films for mammography

Type: Mamoray HDR
Mamoray HDR PQ
Mamoray HDR-C
Mamoray HDR-C Plus
Mamoray HDR-C Plus PQ
Mamoray HT

Application: Mammographic 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 VII in combination with the procedure of Annex V 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.

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/Date/Signature

27-02-2017

Paul Merckx
Director Agfa HealthCare Quality Assurance & Regulatory Affairs
Business Division Imaging

Declaration of Conformity



AGFA HEALTHCARE N.V.

Septestraat 27, 2640 Mortsel, Belgium

declares that the product

Category: Ortho Chromatic Film for screen-film Radiography

Type: CP-GL
Ortho CP-GU
Ortho CP-GU M
Ortho CP-G Plus
Radiolix G Plus

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 VII in combination with the procedure of Annex V 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.

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Position/Date/Signature

13 -05- 2016

Paul Merckx
Director Agfa HealthCare Quality Assurance & Regulatory Affairs
Business Division Imaging

20160513IP_A (Ortho CP Film)

