

Declaration of Conformity

Agfa NV

Septestraat 27, 2640 Mortsel, Belgium

declares that the product

Name: Bermedi X-Ray G

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.

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

03-06-2019



Paul Merckx
Head of Quality Assurance & Regulatory Affairs
Agfa NV