Declaration of Conformity

Agfa NV

SRN Manufacturer BE-MF-000000571

Septestraat 27, 2640 Mortsel, Belgium

Declare under our sole responsibility that the device

Basic UDI-DI:	5414904272985ZC
Product Name:	**G150**
Risk Class (according Annex VIII):	Class I

Intended use: Developer used for the manual processing of medical x-ray film.

is in conformity with the following relevant Union harmonisation legislation:

Regulation (EU) 2017/745 relating to medical devices.
Regulation (EC) 1907/2006 REACH
Regulation (EC) 1272/2008 CLP

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and that the device is in conformity with the following common specification and / or harmonized standards and / or other normative documents:

EN ISO 13485	Quality management standard for medical devices.
EN ISO 14971	Medical devices -- Application of risk management to medical devices.
EN ISO 15223-1	Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.

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Koen Vervoort
Head of Quality Assurance & Regulatory Affairs
Agfa NV

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