

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: **G354**

Risk Class (according Annex VIII): Class I

Intended use: Fixer used for the manual or automatic 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

Declaration of Conformity

Agfa NV

SRN Manufacturer BE-MF-000000571

Septestraat 27, 2640 Mortsel, Belgium

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.

Date of issue: 28/09/2023


Koen Vervoort
Head of Quality Assurance & Regulatory Affairs
Agfa NV

