

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: 5414904273005XE

Product Name: **DRYSTAR DT 2 B**

Risk Class (according Annex VIII): Class I

Intended use: Dry film is intended to display and archive radiographic images by means of a thermographic process using a dedicated HardCopy Dry printer.

Following sizes are available :

(8x10 inch, 10x12 inch, 11x14 inch, 14x14 inch and 14x17 inch)



is in conformity with the following relevant Union harmonisation legislation:

Regulation (EU) 2017/745 relating to medical devices.

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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 systems, requirements for regulatory purposes.
- 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 -- General requirements.
- EN ISO 4090 Medical radiographic cassettes/screens/films and hard-copy imaging films, dimensions and specifications.

This declaration is valid until February 1, 2026.

Mortsel, 01-02-2021

Paul Merckx
Head of Quality Assurance & Regulatory Affairs
Agfa NV

