

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 :
(20x25, 25x30, 28x35, 35x35 and 35x43)



is in conformity with the following relevant Union harmonisation legislation:

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

Declaration of Conformity

Agfa NV

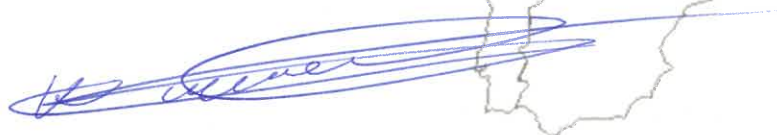
SRN Manufacturer BE-MF-000000571

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 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.

Date of issue: 08/06/2023



Koen Vervoort
Head of Quality Assurance & Regulatory Affairs
Agfa NV

