Declaration of Conformity

Agfa NV

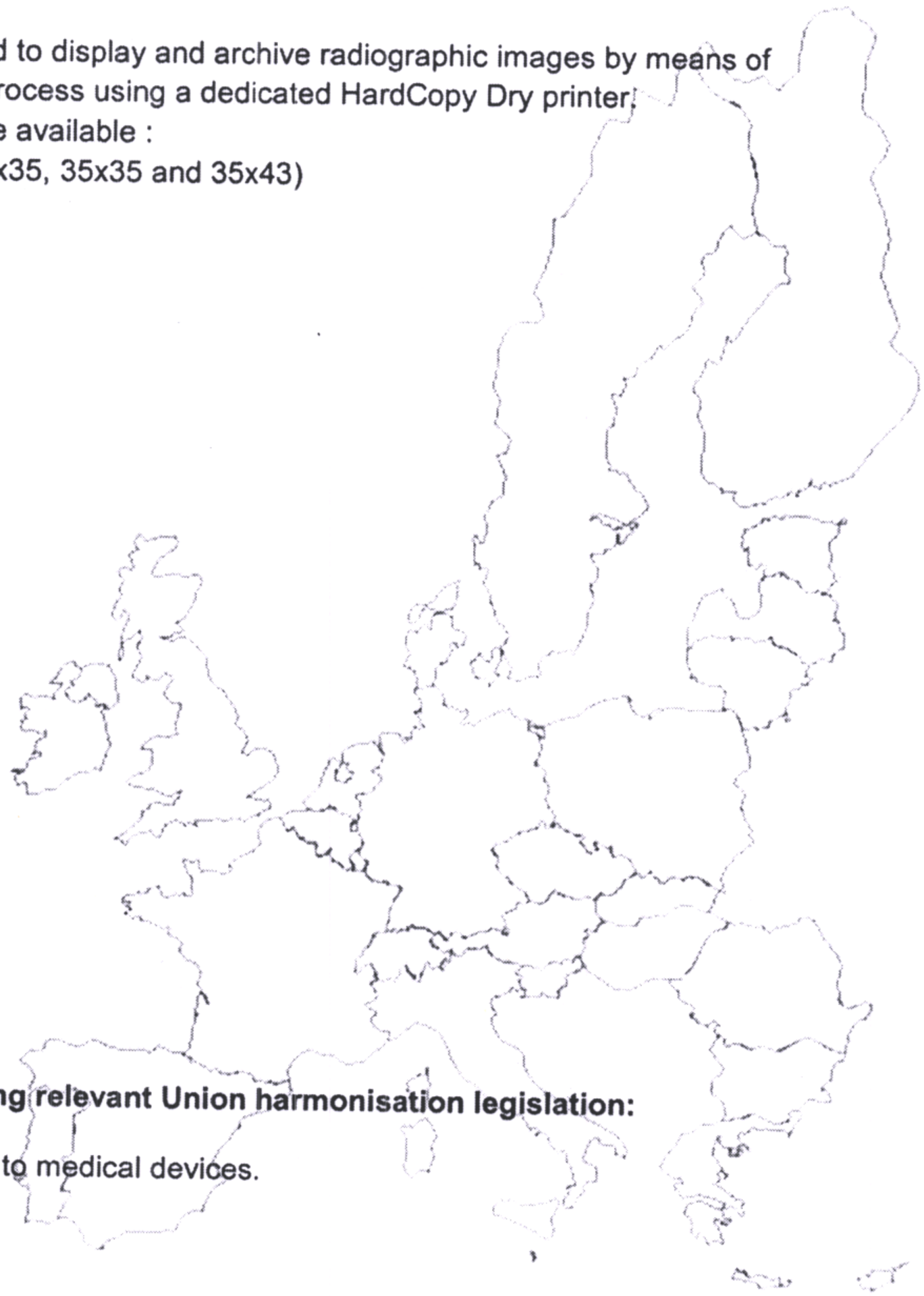
SRN Manufacturer BE-MF-000000571

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.

Digitally signed by Belan Irina
Date: 2025.08.01 11:19:26 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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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 4 August 2027.

Mortsel, 4 August 2022

Paul Merckx
Head of Quality Assurance & Regulatory Affairs
Agfa NV

AGFA