

Declaration of Conformity

Agfa NV

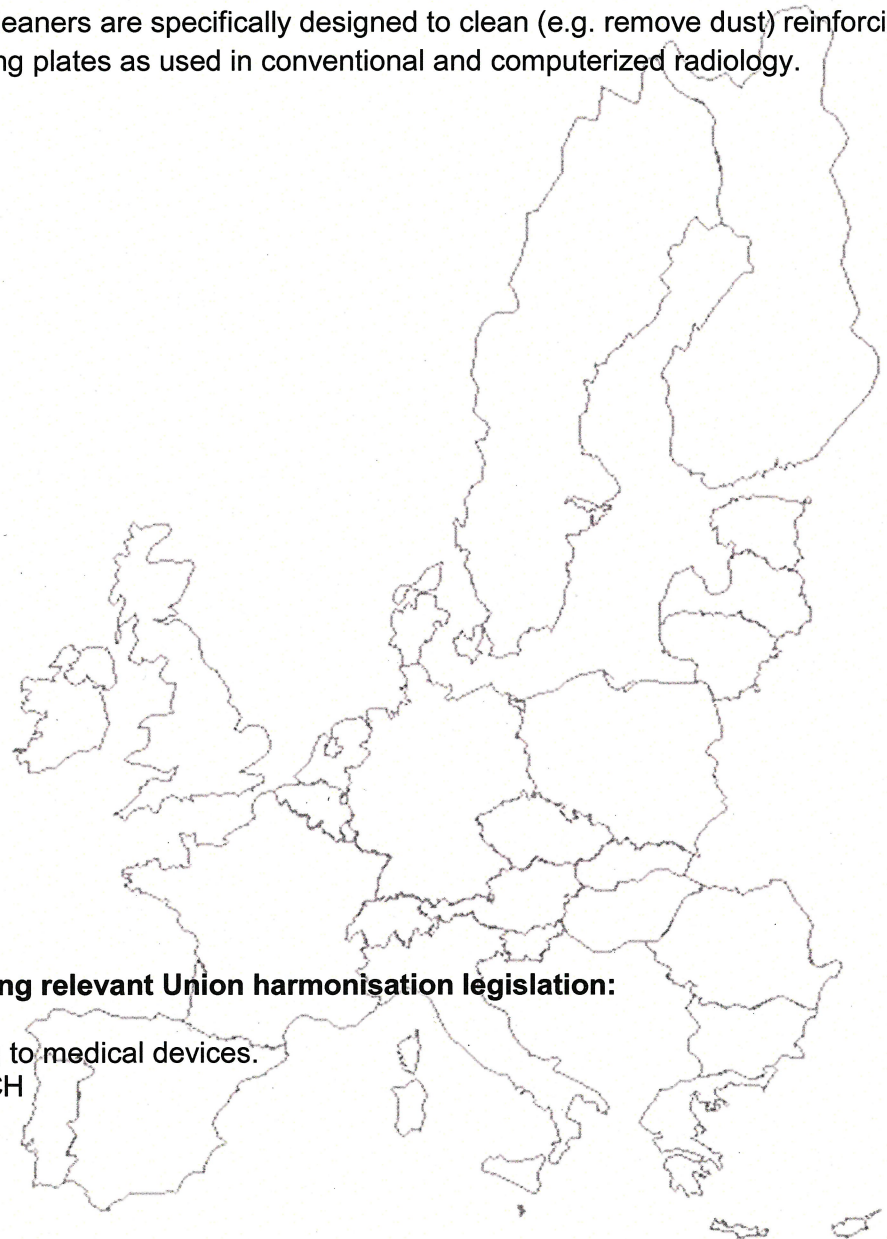
SRN Manufacturer BE-MF-000000571

Septestraat 27, 2640 Mortsel, Belgium

Declare under our sole responsibility that the device

Basic UDI-DI: 5414904272961YW
Product Name: **CAWO Plate Cleaner**
Risk Class (according Annex VIII): Class I

Intended use: Plate and screen cleaners are specifically designed to clean (e.g. remove dust) reinforcing screens and imaging plates as used in conventional and computerized radiology.



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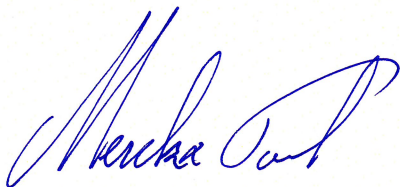
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and that the device is in conformity with the following common specification and / or harmonized standards and / or other normative documents:

- 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.

This declaration is valid until February 1, 2026.

Mortsel, 01-02-2021



Paul Merckx
Head of Quality Assurance & Regulatory Affairs
Agfa NV

