AGFA PRESS RELEASE

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Agfa Radiology Solutions Division receives European Medical Device Regulation certification.

The MDR CE marking confirms Agfa Radiology Solutions compliance with the EU standards required by care providers.

Mortsel, Belgium – 12 July 2022 – 10:00 CET

Highlights include:

- This certification allows Agfa Radiology Solutions to continue innovating its radiology solutions to meet the latest customer needs and requirements.
- The certification is representative of Agfa's commitment and lifecycle approach to safety, backed by clinical data and supported by clinical evaluation, risk management and quality management systems.

Agfa Radiology Solutions is proud to receive the new European Medical Device Regulation (MDR) certification, which was issued by Intertek on 21 June 2022.

"This certification, which covers Agfa's Class IIb X-ray rooms, ensures that Agfa can continue to deliver innovative solutions that help our customers face their real challenges and address their needs and requirements on a day-to-day basis," says Georges Espada, Global Head of Digital Radiography Business Unit of Agfa.

Improving clinical safety and market access

The MDR (Regulation (EU) 2017/745) replaces the former European Medical Device Directive (93/42/EEC), and includes more stringent standards and requirements in both clinical and post-market areas than under the previous regime. The new regulation is intended to create a robust, transparent, sustainable and internationally recognized regulatory framework for clinical safety and fair market access for manufacturers. The MDR ensures alignment

among European member states, and is applicable for the entire lifecycle of the products and the processes supporting the solution delivery.

Continue innovation, without interruption

This certification allows Agfa to continue expanding its Radiology solutions and release innovations in due course. This includes making significant changes to the solutions and adding new functionalities to meet the evolving needs of our customers and the market, as well as allowing them to benefit from state-of-the-art X-ray technologies.

Committed to being the long-term partner of choice for care providers

Paul Merckx, Head of Quality Assurance and Regulatory Affairs, comments: “Agfa is compliant with the latest and most rigorous global quality standards and certification requirements for medical devices, MDR certification is an important accomplishment, it acknowledges the strength of our life-cycle approach to patient and user safety through continuous risk management and clinical evaluation backed up by robust clinical data.”

“The MDR certification is testimony to Agfa’s purpose to provide patients and caregivers with the highest quality healthcare solutions” says Pascal Juéry, President and CEO of Agfa.

About Agfa

Agfa develops, produces and distributes an extensive range of imaging systems and workflow solutions for the printing industry, the healthcare sector, as well as for specific hi-tech industries such as printed electronics & renewable energy solutions.

The headquarters are located in Belgium. The largest production and research centers are located in Belgium, the United States, Canada, Germany, France, the United Kingdom, Austria, China and Brazil. Agfa is commercially active worldwide through wholly owned sales organizations in more than 40 countries.

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for any typographical error.

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