PRESS RELEASE

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Agfa HealthCare among the first to receive new European Medical Device Regulation certification for its Class IIa solutions

The new MDR CE marking confirms Agfa HealthCare's compliance with the highest standards required by care providers.

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- Early certification allows Agfa HealthCare to continue innovating solutions to meet the latest customer needs and requirements, without interruption.
- The certification is representative of Agfa HealthCare's long commitment and lifecycle approach to safety, backed by clinical data and supported by clinical evaluation, risk management and quality management systems.

Agfa HealthCare is proud to be one of the first companies to receive the new European Medical Device Regulation (MDR) certification, which was issued by Intertek on 25 August 2021. This certification, which covers Agfa HealthCare's Class IIa Enterprise Imaging and XERO Viewer solutions, ensures that Agfa HealthCare can continue to deliver to customers innovative solutions that meet their real challenges and address their needs and requirements.

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. The new Regulation is intended to create a robust, transparent, sustainable and internationally recognized regulatory framework for improved 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

Agfa HealthCare's early certification allows the company to continue to expand the Enterprise Imaging platform, its modules and components, and release

innovations without any interruption. 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 IT technologies.

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

Chris Ball, Head of Quality Assurance and Regulatory Affairs, comments, “Agfa HealthCare is compliant with the latest and most rigorous quality standards and certification requirements for medical devices in the world, and MDR certification will be an important qualification criterion. Supported by our clinical evaluation, risk management and quality management systems, our early MDR certification is an acknowledgement of the strength of our life-cycle approach to safety, backed by clinical data.”

“The early certification offers clear proof that Agfa HealthCare is committed and ready to be the long-term partner of choice to our customers,” says Luc Thijs, President of Agfa HealthCare.

- Find out more about the European Medical Device Regulation (MDR).

About Agfa HealthCare

At Agfa HealthCare, we support healthcare professionals across the globe to transform the delivery of care. Our focus is 100% on providing best-of-suite Imaging IT software solutions that enable secure, effective and sustainable imaging data management.

From product development to implementation, our unified Enterprise Imaging Platform is purpose-built to reduce complexity, improve productivity and deliver clinical value. We use our proven track record as an innovator, our in-depth medical knowledge and our strategic guidance to help healthcare providers achieve their clinical, operational and business strategies.