Intrasense announces the certification of Myrian® to the new European regulation (MDR)

Montpellier, France, February 21, 2024 at 5:45 pm CET

Intrasense (FR0011179886 - ALINS), specialist in medical imaging software solutions and developer of Myrian®, is proud to announce that the company has obtained the new CE certification under MDR (European Union Medical Device Regulation 2017/745), authorizing the marketing of the latest version of its Myrian® solution.

New medical device regulations

Myrian® 2.10 is the first version of the Intrasense platform to obtain CE marking under MDR (Medical Device Regulation), the new European regulation for medical devices. On February 17, 2024, the Group received its certificate of conformity covering all 19 Myrian® applications marketed by the company.

Compliance with this new regulation represents a major challenge for all companies operating in the healthcare sector. Intrasense has joined the closed circle of happy recipients of this certificate. Indeed, almost 82% of medical device companies have applied for certification for existing products, but three quarters have not yet obtained their certificate[1].
Certification of the Myrian® 2.10 solution opens new business opportunities in Europe, a particularly promising growth region for the Group.

Myrian® 2.10: innovation and artificial intelligence

Version 2.10 of Myrian® includes a new module dedicated to dental imaging, as well as new artificial intelligence algorithms to simplify examination interpretation and improve patient follow-up.

The company is currently working on the regulatory submission of future versions of Myrian®, including version 2.12, which will bring major innovations such as new artificial intelligence algorithms dedicated to prostate and pulmonary pathologies. Obtaining CE certification under MDR will be accelerated for these next versions thanks to the certificate obtained for version 2.10, and the company is therefore targeting a market launch as early as 2024 for Myrian® 2.12.

[1] SNITEM study "Panorama et analyse qualitative de la filière industrielle des dispositifs médicaux en France", December 2023: https://www.snitem.fr/wp-content/uploads/2024/02/Snitem-Panorama-chiffre-des-DM-2023.pdf

In a few days' time, Intrasense's sales teams will be presenting the new Myrian® products at the ECR (European Congress of Radiology) in Austria, the profession's must-attend trade show, which attracts over 10,000 European and international healthcare professionals every year.

« *The EU-MDR mark for the new version of Myrian® represents an important milestone for Intrasense. Obtaining this certification demonstrates the care we take in developing our products and testifies to our commitment to providing innovative solutions that exceed the most demanding standards and best practices for healthcare technologies. This step opens the door to the acceleration of our roadmap for bringing highly innovative solutions to market* » says **Nicolas Reymond, Intrasense CEO**.

About Intrasense

French expert in medical imaging since 2004, Intrasense develops and markets software platforms in 40 countries, facilitating and securing diagnosis, decision-making and therapeutic follow-up.

Myrian®, an advanced radiology visualization solution, provides 1,200 healthcare establishments with clinical applications to help interpret all types of images. Since 2021, Intrasense has been developing a new platform dedicated to oncology, multidisciplinary and collaborative, to optimize patient care and follow-up.

A Guerbet Group subsidiary since June 2023, Intrasense continues to enrich its solutions by integrating artificial intelligence algorithms in medical imaging. Its teams work closely with healthcare professionals to help save lives.

More information at www.intrasense.fr

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