

DMS GROUP OBTAINS EUROPEAN MDR CERTIFICATION FOR ITS STRATOS BONE DENSITOMETER RANGE

April 7, 2026 – 6:00 pm – Diagnostic Medical Systems (Euronext Growth Paris: FR0012202497 – ALDMS), a specialist in high-performance medical imaging systems for digital radiology and bone densitometry, announces that it has obtained MDR (Medical Device Regulation – Regulation (EU) 2017/745) certification for its entire range of bone densitometers, STRATOS and STRATOS DR.

As the European leader in bone densitometry equipment, DMS Group offers a complete range of solutions, designed and manufactured in France, dedicated to bone health assessment and body composition analysis. This product range stands out for its variety of technologies, designed to meet the requirements of the most advanced clinical practices in evaluation and diagnostic support. The STRATOS range also features a unique intuitive software to optimize workflow, along with a wide range of clinical applications tailored to all use cases and patient profiles.

DMS Group is the only European manufacturer of bone densitometry equipment in a global competitive landscape comprising two North American players and one South Korean player. This gives the Group a strategic and sovereign position not only in Europe, but also across international markets. In 2025, DMS Group generated €11 million in bone densitometry revenue, representing organic growth of +8%.

The MDR certification, issued under the new European regulation applicable to medical devices, confirms that the Group's bone densitometry solutions comply with the latest and most stringent regulatory standards in terms of safety, clinical performance and quality.

This certification marks an important milestone in the execution of DMS Group's regulatory roadmap, while ensuring the continued commercialization of its systems on the European market. The Medical Device Regulation (MDR) replaces the previous Medical Devices Directives (MDD - 93/42/EEC) which has been in force for 25 years.

AN INTERNATIONAL DEVELOPMENT STRATEGY

Building on this regulatory achievement in Europe, DMS Group recently filed a pre-submission application with the U.S. Food & Drug Administration (FDA) for its bone densitometers. This preliminary step aims to initiate discussions with the U.S. regulatory authority ahead of the future submission of its registration file.

The United States represents nearly 40% of the global bone densitometry market, a market in which DMS Group is not present to date with its bone densitometry range.

To date, DMS Group only markets its radiology solutions across the Atlantic. With sales up +71% in 2025, North America was the Group's main growth region during the last fiscal year, driven by agreements with Carestream Health and Fujifilm Healthcare Americas, as well as the first deliveries of the mobile radiology system !M1 through commercial partnerships with Medlink Imaging and JPI Healthcare Solutions.

CONTINUED EXPANSION OF THE PRODUCT OFFERING

DMS Group is also pursuing the regulatory process for its new ONYX mobile radiology system, which is still expected to receive MDR certification in the second quarter of 2026.

With this new mobile radiology platform, the Group intends to strengthen its medical imaging offering and support the evolving needs of healthcare institutions in terms of mobility and flexibility of imaging solutions.

" Obtaining MDR certification for our range of bone densitometers marks an important milestone for DMS Group. It reflects the efforts made by our teams to adapt our products to the new European regulatory requirements. At the same time, the steps initiated with the FDA for the STRATOS range and the progress of the ONYX project illustrate our determination to continue advancing our technologies and gradually expand our presence in international markets. ", says **Samuel Sancerni, Chairman and CEO of DMS Group.**

ABOUT DMS GROUP

DMS Group is a French manufacturer of digital radiology solutions with a strong international focus. It is recognized as a key player and trusted partner across the value chain, both for the quality of its solutions, and for its flexibility, ingenuity and responsible values.

In 2025, DMS Group generated consolidated revenue of €50.0 million, more than 80% of which came from international markets, with a presence on all continents through a network of more than 140 national distributors.

DMS Group is listed on the Euronext Growth Paris market (ISIN: FR0012202497 - ticker: ALDMS) and is eligible for the PEA PME-ETI.

DMS Group is part of the ETIncelles program for SMEs that have the ambition and the desire to become mid-caps.



CONTACTS DMS GROUP

Investor Relations

relationinvestisseur@dms-imaging.com

Press Relations

relationpresse@dms-imaging.com

CONTACTS NEWS

Mathieu OMNES

Analyst and Investor Relations

Tel.: +33 1 53 67 36 92

momnes@actus.fr

Fatou-Kiné N'DIAYE

Press Relations Tel.: +33 1 53 67 36 34

fndiaye@actus.fr