

PRESS RELEASE

PLANET® Onco Dose Receives EU MDR CE Mark certification

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DOSIsoft, SA, a leading provider of patient-specific imaging and dosimetry software solutions for radiation oncology and nuclear medicine, is proud to announce that its latest product release, PLANET® Onco Dose version 3.2 – multi-radionuclide, personalized, voxel-based dosimetry platform for both SIRT and MRT – received Medical Device Regulation (MDR) CE Mark on February 17, 2025, under the new (EU) Regulation 2017/745.

Now available for clinical use across Europe, this advanced software version enhances system openness and flexibility. It allows clinics to cover a broader range of therapies by supporting dose computation for isotopes such as ⁹⁰Y, ¹⁷⁷Lu ¹⁶⁶Ho and ¹³¹I, with the possibility to incorporate others to meet evolving clinical needs. Additionally, clinics can benefit from optimized dosimetry workflows, including the single-time point workflow - reducing workload, enhancing patient comfort, streamlining clinical processes while ensuring reliable accuracy.

PLANET® Onco Dose: All-in-one dosimetry solution dedicated to patient-specific Theranostics

End-to-end, versatile, and vendor-neutral, the novel PLANET® platform is specially designed to integrate multi-radionuclide approaches, implement multi-workflow solutions, and support multi-therapy applications. Clinically validated, its product features—spanning **patient diagnostics, treatment planning, and disease follow-up**—enable highly personalized treatment for each patient.

- **Multi-radionuclide:** Already supporting ⁹⁰Y resin & glass microspheres and ¹⁷⁷Lu, the solution now includes two additional radionuclides, ¹⁶⁶Ho and ¹³¹I, with the flexibility to integrate further beta- and gamma-emitting isotopes under the same certification.
- **Multi-workflow:** Designed to seamlessly integrate into existing clinical workflows, PLANET® Onco Dose supports both **SIRT** (Selective Internal Radiation Therapy) and **MRT** (Molecular Radiation Therapy) dosimetry, covering full 3D and 2D/3D hybrid methods for **multi-time point workflows**, as well as the newly introduced **single-time point workflow** – using a single imaging acquisition to improve workflow efficiency.
- **Multi-therapy:** The platform is suited for a variety of treatments, including ¹⁷⁷Lu-PSMA (prostate-specific membrane antigen) therapy, ¹⁷⁷Lu-PRRT (peptide receptor radionuclide therapy) for neuroendocrine tumors, ⁹⁰Y or ¹⁶⁶Ho radioembolization, ¹³¹I-MIBG for neuroblastoma, radioiodine treatment for hyperthyroidism and thyroid cancer, and more.

Additionally, PLANET® Onco Dose version 3.2 runs on a new operating system with long-term and cybersecurity support, ensuring compatibility with the latest workstation generations. The new release also benefits from GPU acceleration to delivering significantly enhanced performance, compared to previous versions.

DOSIsoft Commitment to EU MDR Compliance

Adopted in April 2017, the Medical Device Regulation (MDR) (EU [2017/745](#)) became applicable in the European Union on May 26, 2021, replacing the previous medical device directives ([93/42/EEC](#) and [90/385/EEC](#)). This regulation reshapes the European legal framework for medical devices.

DOSIsoft is actively engaged in **supporting MDR implementation**. The company has reinforced its **internal Quality System** to align with the updated regulatory landscape, reaffirming its commitment to the highest standards of **safety, performance, and compliance**.

"It is a real achievement and a collective work for DOSIsoft to provide all answers to our notified body, along with updated technical documentation and additional performance and clinical data," highlights Marc USZYNSKI, CEO at DOSIsoft S.A., "This new version of [PLANET® Onco Dose](#), fully compliant with the EU MDR requirements, positions PLANET® ahead of the competition. We are looking forward to seeing patients across the EU Mark region benefit from this safe and effective device."

"From clinical research perspective, the hospital centers can access the new functionality IBSI-compliant (Image Biomarker Standardization Initiative) texture radiomics, through current integrated PLANET® platform to carry out diagnostics, analytics, and AI-based innovative research projects. This new feature and the global PLANET® development program are also perfectly aligned with DOSIsoft participation in the [EU Thera4Care](#) project, aiming at transforming cancer treatment through the power of radiotheranostics." adds Marc USZYNSKI.

To learn more about PLANET® Onco Dose, the patient-specific Theranostics solution, visit DOSIsoft at JFMN (Booth #6a, March 20–23, 2025), as well as at upcoming SNMMI, EANM Annual Meetings, and other key nuclear medicine events.

About Regulation (EU) 2017/745

The regulation aims to ensure the smooth functioning of the internal market as regards medical devices, taking as a base a high level of health protection for patients and users, and taking into account the small- and medium-sized enterprises that are active in this sector. At the same time, this Regulation sets high standards of quality and safety for medical devices in order to meet common safety concerns as regards such products.

About PLANET®

PLANET® Onco Dose Edition 3 is developed by DOSIsoft SA in France. It is a Class IIb CE-marked medical device under MDR (EU) 2017/745 and is currently FDA 510(k) pending. Availability of the product or specific features may vary by country and regulatory approval status.

CE MDR Certificate No. 40168 was issued by GMED, a notified body with identification number CE 0459.

About DOSIsoft

Founded in 2002, DOSIsoft stands as market leader specialized in dosimetry software in Radiation Oncology and Nuclear Medicine to improve cancer patient safety & treatment quality. We provide the most competitive patient-specific quality assurance and medical imaging solutions in over 600 hospital centers in 60 countries. Spin-off between Gustave Roussy and Curie Institute in France, DOSIsoft constantly innovates in partnership with the major cancer institutes and research centers in the world. www.dosisoft.com

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