

Press Release

Strasbourg, September 21, 2026

World First

CE Class IIa Marking

Pixacare Obtains CE Class IIa Marking for Its Chronic Wound Analysis AI

WoundTrack II is the **first wound analysis AI software certified as a Class IIa medical device** by a notified body. It addresses a concrete need shared by care teams, healthcare facilities, and clinical research: objectively measuring chronic wounds, standardizing their monitoring, and ensuring reliable documentation.

MDR Certificate Issued

March 16, 2026

DNV · 2460

Notified body — DNV Product Assurance AS

EU 2017/745

Annex IX (Chap. I & III) of the MDR Regulation

French medtech company **Pixacare**, publisher of Pixacare Application, an AI-assisted wound care monitoring platform, announces that **WoundTrack II**, its AI-powered wound analysis module, has obtained CE Class IIa marking¹.

Already deployed in **more than 70 hospitals and clinics across Europe** — including Lille University Hospital, Gustave Roussy, and Liège University Hospital — with more than 2 million lesions documented and over 250,000 patients monitored, the solution reaches a **major regulatory milestone** set to accelerate its international adoption.

Context

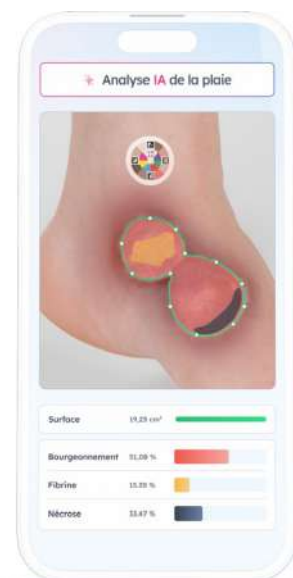
- **1.2 million people** live with a chronic wound in France² — diabetic foot ulcers, leg ulcers, pressure injuries — nearly 2 million when including complex wounds³.
- Their care costs approximately **€1 billion per year** for the French national health insurance system alone⁴.
- Globally, the wound care market is estimated at **\$18.5 billion** in 2022, with a projection of \$30 billion by 2030⁵.
- Manual measurement (length × width) **overestimates wound area by approximately 40%** compared to reference digital planimetry⁶.

AI That Measures, Analyzes, and Assists Without Replacing the Clinician

WoundTrack II is medical device software designed to automatically analyze photographs of chronic wounds: it **delineates the wound**, **calculates its surface area in cm²**, and **identifies tissue composition** (granulation tissue, fibrin, necrosis) using artificial intelligence algorithms.

Every segmentation remains **under human supervision**: the algorithm proposes an initial outline, which the clinician corrects if needed and validates before measurements are calculated. This hybrid AI-plus-clinician approach combines the speed of automation with the reliability of medical expertise.

WoundTrack II operates as an add-on module to Pixacare Application: photos taken and organized through the platform are automatically analyzed, with results displayed directly in the clinician's interface. Facilities already using Pixacare Application — deployed since 2021 in French hospitals and clinics — can access WoundTrack II **without changing their existing workflow**.



Three Benefits of Reliable Measurement

For patients: a poorly measured wound is a poorly monitored wound, with an increased risk of complications, infection, wound extension, delayed healing, and — for diabetic foot wounds — amputation⁷.

For healthcare facilities: national regulatory frameworks are evolving, with several markets now making reimbursement for wound care procedures contingent on precise, standardized documentation. Pixacare directly addresses this need by automating the production of standardized reports.

For clinical research: standardized, reproducible measurement such as WoundTrack II's is a prerequisite for obtaining optimized data in wound-healing clinical studies (evaluating dressings, creams, or other treatments).



A One-of-a-Kind Certification

Obtaining CE Class IIa marking is the culmination of nearly four years of exchanges between Pixacare and DNV Product Assurance AS, its notified body. The challenge lies in how new this field is: having a wound analysis AI evaluated as a genuine medical device remains largely uncharted territory, requiring adaptation on both sides.

To our knowledge, as of the publication date, WoundTrack II is **the first wound analysis solution to achieve this level of certification worldwide**, and **the only one authorized in the European market as a Class IIa device** under the MDR regulation. It was evaluated as a medical device by a notified body — an accredited third party that independently verifies the safety, performance, and quality management system of the manufacturer, certified to ISO 13485:2016.

Accelerated Adoption, Eyes on International Growth

CE Class IIa certification represents, for healthcare facilities and medtech companies alike, a **decisive regulatory assurance** in their decision-making process.

In Switzerland, **Cutempa Medical**, a Basel-based medtech company developing a mineral-based dressing technology for chronic wounds and diabetic foot, signed with Pixacare at the start of summer to access WoundTrack II, explicitly citing **CE Class IIa marking as a condition for adoption**.

Rodday Wundmanagement, one of Germany's leading home wound care providers, with several hundred wound and healing specialist nurses across Germany and Switzerland, also signed following the certification — the first concrete signal of the international acceleration made possible by this European marking.

What They're Saying



"Pixacare's vision starts from an observation: chronic wounds are a largely invisible health issue, yet their impact is considerable — on public finances, on caregivers' time, and on patients' quality of life. We firmly believe that digital technology and AI can help address this: structured documentation, objective measurements, and, in time, decision support for dressing selection. But these tools cannot be mere software: they must meet the highest standards of clinical performance and safety. That's why we invested significant resources to obtain this marking, which makes WoundTrack II, to our knowledge and as of the publication date, the first wound analysis tool to be evaluated as a medical device by a notified body. It's the foundation we want to build on: becoming the global leader in AI-assisted wound care monitoring."

Matis Ringdal

CEO and Co-founder of Pixacare



"Class IIa MDR certification reflects what we've championed from the start: artificial intelligence in service of care, built on clinical evidence and evaluated to the same standards as any medical device. Our human-supervision approach illustrates this — AI assists the clinician; it does not replace them."

Professor Frédéric Bodin

Co-founder, Chief Scientific and Medical Officer of Pixacare · Head of Plastic, Reconstructive and Maxillofacial Surgery, Strasbourg University Hospital



"Until now, Pixacare allowed us to ensure traceability and monitoring of chronic wounds. Validating the AI modules takes this a step further: it enables reliable wound quantification, and therefore optimized care. By keeping the clinician in the loop to verify the algorithm, it secures the protocol in complex cases and under the most demanding imaging conditions — particularly with darker skin tones."

Dr Guillaume Maxant

Vascular Surgeon, Haguenau Hospital Center · Author of the Pixaire1 study, *Evaluation of automated chronic wound surface measurement systems*⁸

About Pixacare

Pixacare is the French medtech company behind AI-assisted wound care monitoring, and the European market leader in its category. Founded in 2019 in Strasbourg, the company develops a platform that enables healthcare professionals — in hospitals and community practice alike — to organize their medical photos and videos, standardize clinical documentation (photos, questionnaires, measurements, and reports integrated into the patient record), and remotely monitor patient wound healing via SMS, with notifications sent to caregivers in the event of complications.

At the heart of the solution is WoundTrack II, an AI system marked CE Class IIa (notified body no. 2460), which automatically measures wound surface area and analyzes tissue composition (granulation tissue, fibrin, necrosis). It is a decision-support tool that does not replace the judgment of a healthcare professional. Pixacare meets the strictest regulatory requirements: a quality management system certified to ISO 13485:2016, CE Class IIa marking, a European patent, certified secure health data hosting, and GDPR compliance.

+70

hospitals and clinics

6

countries

+250,000

patients monitored

+2M

lesions documented

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Photos, logos, and high-resolution visuals are available on request from the press contact, along with any additional information.

Sources

- 1 DNV certificate no. C769484, issued March 16, 2026, valid until March 16, 2031. Conformity assessed under Annex IX (Chapters I & III) of Regulation (EU) 2017/745.
- 2 HAS (French National Authority for Health) and PMSI (French Hospital Discharge Database) data — 1.2 million people living with a chronic wound in France, including venous leg ulcers (42%), arterial or mixed ulcers (24%), pressure injuries (23%), and diabetic foot wounds (11%).
- 3 Société Française et Francophone des Plaies et Cicatrisations (SFFPC) — cicatrisations.org/association-organisatrice: “chronic and complex wounds: nearly 2 million people affected.”
- 4 La Revue du Praticien, “Plaies chroniques” — larevuedupraticien.fr; see also the chronic wound care guide developed by Assurance Maladie (French National Health Insurance) with the SFFPC, validated by the HAS.
- 5 EWMA (European Wound Management Association), Summary of Wound Prevalence, citing Fortune Business Insights.
- 6 Rogers et al., cited in “Wound Measurement Techniques: Comparing the Use of Ruler Method, 2D Imaging and 3D Scanner,” PMC4495754; see also PMC2909508.
- 7 Assurance Maladie and SFFPC, “Plaies chroniques: prise en charge en ville,” a practice support tool validated by the HAS — ameli.fr/infirmier/exercice-liberal/memos/suivi-ville-plaies-chroniques: standardized wound assessment and description at each dressing change guide treatment adjustments and referral to a specialist. See also SFFPC — sffpc.org/news: a worsening wound is a sign of progressive disease and requires prompt diagnosis.
- 8 Maxant et al., *Evaluation of automated chronic wound surface measurement systems* (Pixaire1 study) — medrxiv.org/content/10.64898/2026.03.30.26344793v1.