

Menstrualia Gets CE Mark for Sobek, Takes Aim at Earlier Women's Health Diagnostics

Backed by Invitalia, the Italian femtech startup is preparing clinical pilots to explore earlier chronic disease assessment and women's health prevention.

MILAN, LOMBARDY, ITALY, August 5, 2026 /EINPresswire.com/ -- Women's health has long been underserved by healthcare innovation, particularly when it comes to chronic diseases that are difficult to diagnose in their early stages. For women living with conditions such as endometriosis, the path from first symptoms to diagnosis can be long and uncertain.

Menstrualia, a Northern Italian femtech startup founded by Franziska Roessler, is taking a different approach. The company is developing Sobek, a non-invasive diagnostic device that combines blood and saliva biomarkers to explore whether biological changes linked to chronic disease can be identified earlier.

The company has now secured CE marking for its Sobek diagnostic device, enabling Menstrualia to place the device on the European market in accordance with applicable EU medical device requirements.

That regulatory milestone puts the startup in a position to move from product development toward the next, and potentially more important, stage: clinical validation.

Menstrualia is currently in discussions with clinical associations, hospitals, clinics, and diagnostic laboratories to establish pilot programs for its SBK Test. The aim is to generate the first real-world clinical evidence, evaluate test performance, and understand whether the technology could eventually complement existing approaches to chronic disease assessment and women's health prevention.

"We see the CE Mark for Sobek as an important milestone, but the real work begins now," said Franziska Roessler, Founder and CEO of Menstrualia. "We are working with clinical partners to develop pilot programs that will help us generate real-world evidence and better understand how our approach could contribute to a more proactive model of women's health. Our goal is to build the clinical evidence needed to understand where this technology can create meaningful value for patients and healthcare professionals."

A Different Approach to Women's Health Prevention

The idea behind Mestrualia is relatively simple: healthcare is often better at treating established disease than identifying meaningful biological changes early enough to support proactive care.

Chronic diseases affecting women can be particularly difficult to assess because symptoms are not always specific and existing diagnostic pathways can be lengthy. Endometriosis is one example, but Mestrualia's ambition extends beyond a single condition.

The company's Sobek platform uses a dual-sample approach, combining blood and saliva analysis to investigate biological signals that may be associated with early physiological changes.

The technology is still under clinical evaluation. Mestrualia is not claiming that Sobek can prevent chronic disease or replace established diagnostic methods. Instead, the company is exploring whether its biomarker approach could eventually provide clinicians with additional objective information to support earlier assessment and monitoring.

That distinction is central to the company's strategy. The CE marking provides the regulatory pathway to place Sobek on the European market, but clinical studies will be needed to determine the technology's actual performance and potential value in healthcare.

For Mestrualia, women's health is the initial focus. Endometriosis is among the first areas where the company intends to explore the technology, while the longer-term vision is broader: using biomarker-based diagnostics to support earlier detection, prevention-oriented healthcare, and chronic disease monitoring.

CE Marking Is Only the Beginning

For an early-stage medical technology company, regulatory approval can be a major milestone. For Mestrualia, however, the CE marking is being positioned as the start of the next phase rather than the end of development.

The company's quality management framework is based on ISO 13485, the internationally recognized quality management standard for medical devices, complemented by risk management processes under ISO 14971.

Mestrualia is now working to build the clinical evidence around Sobek.

The planned pilot studies will investigate how the SBK Test performs in real-world healthcare environments, how biomarker results correlate with clinical findings, and whether the technology could potentially support earlier assessment and monitoring of chronic diseases.

The company is also speaking with diagnostic laboratories about integrating blood and saliva

sample processing into existing laboratory infrastructure and workflows.

At the same time, Mestrualia is engaging with clinical and patient organizations, particularly those working in endometriosis and chronic disease awareness, to help ensure that future studies address real-world clinical needs.

Backed by Invitalia

Mestrualia's development has received support from Invitalia, the Italian National Agency for Development, alongside regional innovation funds in Northern Italy.

The backing comes as the company transitions from developing its technology toward clinical validation and commercial preparation.

The potential opportunity is not limited to a single disease. If clinical studies demonstrate that the biomarker approach can provide reliable and useful information, the platform could potentially support a broader model of women's health prevention and chronic disease assessment.

But for now, the focus is on evidence.

The upcoming clinical pilots will help determine whether Sobek can move from a promising technology to a clinically useful tool that fits into existing healthcare pathways.

What's Next for Mestrualia

Mestrualia is building partnerships around three priorities:

Clinical Validation: Working with hospitals, clinics, and clinical associations to develop pilot studies and generate the first real-world evidence for the SBK Test.

Laboratory Integration: Collaborating with diagnostic laboratories to explore sample processing, workflow integration, and potential scalability.

Women's Health Partnerships: Engaging with patient organizations focused on endometriosis and chronic disease awareness to ensure clinical relevance and patient-centered development.

The results will be an important test for Mestrualia's broader vision of women's health prevention.

For Franziska Roessler and the Mestrualia team, the next step is not to claim that Sobek has already changed women's healthcare. It is to generate the clinical evidence needed to understand whether it can.

About Mestrualia

Founded by Franziska Roessler, Mestrualia is a Northern Italian femtech company developing diagnostic technologies focused on women's health, women's health prevention, and chronic disease assessment and monitoring.

The company's Sobek platform uses proprietary biomarker analysis combining blood and saliva samples to investigate biological changes associated with chronic health conditions.

With an initial focus on women's health and conditions such as endometriosis, Mestrualia's longer-term vision is to contribute to earlier detection, prevention-oriented healthcare, and improved monitoring of chronic diseases through accessible biomarker-based diagnostics.

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