



NEWS RELEASE

# Natera Announces IVDR Certification for Signatera™ Across Multiple Cancers

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Signatera is the first personalized molecular residual disease (MRD) test for solid tumors to receive IVDR certification in the EU

AUSTIN, Texas--(BUSINESS WIRE)-- **Natera, Inc.** (NASDAQ: NTRA), a global leader in cell-free DNA and precision medicine, today announced that Signatera has received certification as a Class C device under the European Union's In Vitro Diagnostic Regulation (IVDR).

The IVDR represents one of the world's most rigorous regulatory frameworks for in vitro diagnostic medical devices, replacing the outgoing In Vitro Diagnostic Medical Devices Directive (IVDD). To obtain certification, the Signatera platform — including the assay, specimen collection kit, and associated software — underwent a comprehensive review against some of the most stringent standards in the medical industry, including evidence of analytical and clinical validity, as well as quality system management.

IVDR certification reduces the lead time and regulatory overhead for launching new clinical trials, and it ensures that Natera can continue offering Signatera to EU patients after the IVDD transition deadline in 2028.

Under this certification, Signatera is indicated for use in the adjuvant and surveillance settings across gastrointestinal malignancies, genitourinary malignancies, non-small cell lung cancer, head and neck cancer, breast cancer, skin cancer, gynecological malignancies, diffuse large B-cell lymphoma, indolent non-Hodgkin's lymphomas, and pan-cancer immunotherapy monitoring.

Certification was supported by extensive clinical and analytical evidence demonstrating Signatera's performance



across multiple tumor types and clinical settings. It follows two significant regulatory milestones for the Signatera portfolio: in June 2026, Signatera received approval from Japan's Pharmaceuticals and Medical Devices Agency (PMDA) for patients with colorectal cancer; and in May 2026, the U.S. Food and Drug Administration approved Signatera™ CDx as a companion diagnostic for patients with muscle-invasive bladder cancer.

"MRD testing is redefining how we assess recurrence risk and guide treatment decisions for patients with cancer," said Julien Taieb, M.D., Ph.D., head of the gastroenterology and gastrointestinal oncology department at the Université Paris-Cité. "This certification for Signatera is an important milestone as it will enhance access to personalized MRD testing for patients across Europe within a more rigorous regulatory framework."

"Achieving IVDR certification is a key milestone in Natera's plan to bring Signatera MRD testing to Europe," said Solomon Moshkevich, president, clinical diagnostics at Natera. "Backed by extensive clinical evidence across multiple cancer types, this builds on our recent regulatory approvals in both the United States and Japan."

## About Natera

Natera™ is a global leader in cell-free DNA and precision medicine, dedicated to oncology, women's health, and organ health. We aim to make personalized genetic testing and diagnostics part of the standard-of-care to protect health and inform earlier, more targeted interventions that help lead to longer, healthier lives. Natera's tests are supported by more than 400 peer-reviewed publications that demonstrate excellent performance. Natera operates ISO 13485-certified and CAP-accredited laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) in Austin, Texas, and San Carlos, California, and through Foresight Diagnostics, its subsidiary, operates an ISO 27001-certified and CAP-accredited laboratory certified under CLIA in Boulder, Colorado. For more information, visit [www.natera.com](http://www.natera.com).

## Forward-Looking Statements

All statements other than statements of historical facts contained in this press release are forward-looking statements and are not a representation that Natera's plans, estimates, or expectations will be achieved. These forward-looking statements represent Natera's expectations as of the date of this press release, and Natera disclaims any obligation to update the forward-looking statements. These forward-looking statements are subject to known and unknown risks and uncertainties that may cause actual results to differ materially, including with respect to our efforts to develop and commercialize new product offerings, whether the results of clinical or other studies will support the use of our product offerings, the impact of results of such studies, our expectations of the reliability, accuracy, and performance of our tests, or of the benefits of our tests and product offerings to patients, providers, and payers. Additional risks and uncertainties are discussed in greater detail in "Risk Factors" in Natera's recent filings on Forms 10-K and 10-Q, and in other filings Natera makes with the SEC from time to time. These

documents are available at [www.natera.com/investors](http://www.natera.com/investors) and [www.sec.gov](http://www.sec.gov).

Investor Relations: Mike Brophy, CFO, Natera, Inc., [investor@natera.com](mailto:investor@natera.com)

Media: Lesley Bogdanow, VP of Corporate Communications, Natera, Inc., [pr@natera.com](mailto:pr@natera.com)

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