



PRESS RELEASE

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Biocartis Receives European IVDR Certification for the Idylla™ CDx MSI Test

*Idylla™ CDx MSI Test is the Second Fully Automated Companion Diagnostic Test
Approval for Biocartis under IVDR*

Mechelen, Belgium, 10 March 2026 – Today, Biocartis announced that its [Idylla™ CDx MSI Test](#) has received Class C companion diagnostic (**CDx**) certification under the EU's **IVDR**¹ as a CDx for colorectal cancer (CRC).

The Test is indicated as an aid to identify adult patients with **microsatellite instability-high (MSI-H) metastatic CRC patients**, who may benefit from treatment with **nivolumab in combination with ipilimumab**.

Designed for use on the [Idylla™ Platform](#), the Idylla™ CDx MSI Test qualitatively detects MSI-H/MSS in CRC tissue samples within a single-use cartridge, requiring less than **three minutes** of hands-on-time and delivering straightforward results in under **three hours**. For more information about the test, please visit the [Biocartis website](#) or [contact the Biocartis team](#).

Roger Moody, Chief Executive Officer of Biocartis, commented: "*In [May 2025](#), we received IVDR certification for the [Idylla™ EGFR Mutation Test](#) and have now expanded our IVDR-approved portfolio with the Idylla™ CDx MSI Test. Building on its [FDA approval in the United States](#), the Idylla™ CDx MSI Test is now also empowering clinicians across Europe with rapid and reliable results that support groundbreaking therapy selection for CRC patients, enabling timely and informed treatment decisions when every moment counts.*"

The IVDR-certified Idylla™ CDx MSI Test will be available soon to customers across Europe and additional regions where IVDR regulations apply. The Idylla™ CDx MSI Test is already commercially [available in the US](#).

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¹ European In Vitro Diagnostic Medical Device Regulation (EU) 2017/746 (IVDR).

About Biocartis

Biocartis is committed to helping cancer patients worldwide access the right treatment faster. With our proprietary Idylla™ Platform, we deliver in-house molecular biomarker results in only 3 hours, enabling healthcare professionals to make timely, informed decisions that guide personalized therapy. Our expanding portfolio of diagnostic tests and research assays addresses key unmet clinical needs across multiple cancers, including lung, skin, thyroid, colorectal, endometrial, blood, brain, and breast cancer.

Learn more at www.biocartis.com and follow us on [LinkedIn](#), [Facebook](#) and [X \(Twitter\)](#).

Disclaimers

Idylla™ Platform is CE-marked in Europe in compliance with EU IVD Regulation 2017/746, listed as a class II device in the US under establishment registration 3009972873, and registered in many other countries. Idylla™ CDx MSI Test (A0220/6) is CE-marked in Europe in compliance with the EU IVD Regulation 2017/746 (IVDR) and is approved in the US under P250005. Biocartis and Idylla™ are registered trademarks in Europe, the US and many other countries. The Biocartis and Idylla™ trademarks and logos are used trademarks owned by Biocartis NV. © March 2026, Biocartis NV. All rights reserved.