

Omega Bio-tek Releases IVDR-Compliant Reagents and Kits for Use in the European Union

NORCROSS, GEORGIA, USA, January 24, 2023 /EINPresswire.com/ -- Today, Omega Bio-tek, a leader in nucleic acid purification kit manufacturing, announces its release of [IVDR](#) compliant reagents and Kits for use in the European Union.



This launch of IVDR-compliant Class A products ensures that labs in the EU that rely on Omega Bio-tek kits and reagents in their diagnostic workflows will continue to be able to use these products without disruption.

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Omega Bio-tek shares the European Commission's commitment to the highest quality standards. We remain committed to providing high-throughput solutions scientists in the EU rely on.”

Richard Blomgren, Quality Assurance Manager

The [In Vitro](#) Diagnostic Regulation (IVDR) (EU) 2017/746 is a new, harmonized regulatory framework established to ensure the present and future safety and performance of in vitro diagnostic (IVD) medical devices in the European Union market. The IVD Regulation replaces the previous IVDD directive, under which these Omega Bio-tek products have been CE-IVD marked.

“Omega Bio-tek shares the European Commission's commitment to the highest standards of quality,” said Richard Blomgren, Quality Assurance Manager at Omega Bio-tek. “We remain committed to providing high-throughput solutions for delivering the nucleic acid

purification results scientists in the EU rely on.”

Omega Bio-tek Class A IVDR-compliant products span a repertoire of nucleic acid purification products, including kits for cfDNA, high-volume blood [DNA](#), blood and tissue DNA, and viral DNA and RNA.

<https://www.omegabiotek.com/company/ce-ivd-products/>

About Omega Bio-tek, Inc.

Omega Bio-tek, founded in 1998, is an ISO 9001:2015 and ISO 13485:2016 certified, industry-leading manufacturer of DNA/RNA purification kits for clinical, biotechnology, and genomics research. With a diversified product portfolio for low-throughput to high-throughput purification, Omega Bio-tek kits purify high-quality nucleic acids from a wide variety of samples. Omega Bio-tek's products and services are used in thousands of universities and research institutes in over 100 countries worldwide.

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