# Eurobio Scientific becomes one of the first European companies to obtain IVDR[1] CE marking of PCR tests

- **Fundamental milestone successfully completed**
- **Competitive advantage in a more restrictive regulatory environment**
- **New demonstration of Eurobio Scientific know-how**

**Paris, May 23, 2023 – 5h45 pm**

**Eurobio Scientific** (FR0013240934, ALERS, PEA-PME eligible), a leading French group in *in vitro* specialty medical diagnostics and life sciences, announces today that it obtained in April 2023 the first IVDR CE markings for PCR tests from its EurobioPlex line, thus becoming one of the first European companies to obtain such marking for its own products.

## IVDR CE marking of PCR tests

As part of the new IVDR regulation, Eurobio Scientific has received IVDR CE markings that allow the marketing of the first 3 PCR tests from its EurobioPlex line as class C *in-vitro* diagnostic medical devices, requiring expertise in molecular diagnostics of infectious diseases.

The other tests in the EurobioPlex line, which were already CE marked according to the old regulation (Directive 98/79/EC) before May 26, 2022, benefit from an extension period which allows them to be marketed until obtaining their IVDR CE marking which must take place no later than May 2025 for class D devices (diseases presenting a high risk, HIV, hepatitis, etc.), May 2026 for class C, and May 2027 for class B and A sterile.

## Achievement of IVDR ISO certification

This CE marking follows the company's annual audit by its French notified body, GMED, during which its ISO 13485:2016 certification was renewed for 3 years (certificate N°39268 rev. 0) with a quality management system that complies with the requirements of regulation (EU) 2017/746 – IVDR which imposes new, more restrictive rules for maintaining the certification and CE marking of products. This system covers all operational aspects of Eurobio Scientific, in France, related to the processes and procedures that ensure the quality and performance of the PCR tests produced by the company, a mandatory prerequisite to comply with the new IVDR requirements.

This ISO certification was obtained for "*in-vitro* diagnostic devices: kits, reagents and control materials intended to be used to detect the presence of an infectious agent or exposure to such an agent, including sexually transmitted agents". It therefore allows Eurobio Scientific to proceed sequentially with the new CE marking of its current infectious disease PCR tests, and to CE mark its future tests within the IVDR framework which now applies to all new *in-vitro* diagnostic medical devices.

## A critical know-how

CE marking and ISO certification in France according to the new, more stringent European standards represent a fundamental step in the Group's development, as they complement the similar certification that its subsidiary, GenDx, was the first to obtain in the Netherlands. This step confirms

[1] The new European IVDR regulation replaces Directive 98/79/EC and is applicable in all EU countries. It aims to ensure the proper functioning of the internal market for in vitro diagnostics medical devices, based on a high level of health protection for patients and users, and sets high standards for the quality and safety of in vitro diagnostics medical devices in order to address the common safety issues relating to these products.

the Group's strong regulatory expertise, which is becoming a major asset for successfully developing and marketing new diagnostic tests, regardless of their origin in Europe.

With this now critical know-how, the Group demonstrates that it was able, in a very short time, to raise the quality requirements for its own products and successfully complete much more complex regulatory processes. Eurobio Scientific has thus built up a real high-value asset to ensure its future development.

*« Getting of our new IVDR certification as well as the IVDR CE marking of the first 3 tests in our EurobioPlex line, constitute the culmination of a process of strengthening our quality and regulatory system which had already been underway for several years. I would like to thank here our employees without whom this major step for Eurobio Scientific would not have been possible, especially since this qualification is also a strong signal that we send to our partners and customers regarding the quality of our teams and our products. »* says Cathie Marsais, Vice President of Operations at Eurobio Scientific.

## Next financial meetings

Annual Shareholders' meeting: June 13, 2023

---

**About Eurobio Scientific**

Eurobio Scientific is a key player in the field of specialty in vitro diagnostics. It is involved from research to manufacturing and commercialization of diagnostic tests in the fields of transplantation, immunology and infectious diseases, and sells instruments and products for research laboratories, including biotechnology and pharmaceutical companies. Through many partnerships and a strong presence in hospitals, Eurobio Scientific has established its own distribution network and a portfolio of proprietary products in the molecular biology field. The Group has approximately 250 employees and four production units based in the Paris region, in Germany, in the Netherlands and in the United States, and several affiliates based in Dorking UK, Sissach Switzerland, Bünde Germany, Antwerp Belgium and Utrecht in The Netherlands.
Eurobio Scientific's reference shareholder is the EurobioNext holding company which brings together its two directors, Jean-Michel Carle and Denis Fortier, alongside the "Pépites et Territoires" by AXA & NextStage AM investment program, managed by NextStage AM.

For more information, please visit: www.eurobio-scientific.com

The company is publicly listed on the Euronext Growth market in Paris
Euronext Growth BPI Innovation, PEA-PME 150 and Next Biotech indices, Euronext European Rising Tech label.
Symbol: ALERS - ISIN Code: FR0013240934 - Reuters: ALERS.PA - Bloomberg: ALERS:FP

**Contacts**

**Groupe Eurobio Scientific**
Denis Fortier, General Manager
Hervé Duchesne de Lamotte, General Manager
Tel. +33(0) 1 69 79 64 80

**Calyptus**
Mathieu Calleux
Investors Relations
Tel. +33(1) 53 65 68 68 - eurobio-scientific@calyptus.net