

DIASORIN SUBMITS THE LIAISON NES[®] POINT-OF-CARE MOLECULAR DIAGNOSTICS SYSTEM AND 4-PLEX RESPIRATORY PANEL TO THE FDA FOR 510(K) CLEARANCE AND CLIA WAIVER

DIASORIN HAS SUBMITTED:

- 510(K) PRE-MARKET NOTIFICATION FOR THE FIRST MOLECULAR DIAGNOSTIC POINT-OF-CARE (POC) PLATFORM OF THE GROUP, THE LIAISON NES[®]
- 510(K) PRE-MARKET NOTIFICATION FOR A 4-PLEX RESPIRATORY PANEL ON THE PLATFORM
- CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) WAIVER APPLICATION

Saluggia, Italy – July 2, 2025 - Diasorin (FTSE MIB: DIA) announces the submission of a 510(k) premarket notification and CLIA waiver application to the U.S. Food and Drug Administration (FDA) for its LIAISON NES[®], a next-generation molecular POC testing platform.

The submission covers the LIAISON NES[®] FLU A/B, RSV & COVID-19 panel, designed to simultaneously detect and differentiate four of the most common and clinically significant respiratory pathogens: influenza A, influenza B, SARS-CoV-2, and respiratory syncytial virus (RSV).

The LIAISON NES[®] system is designed to provide laboratory-quality molecular results, delivering high diagnostic accuracy with the speed and simplicity needed at the POC. Its compact footprint, intuitive workflow, and connectivity features make it ideally suited for decentralized settings such as urgent care centers, emergency departments, and physician offices.

“This submission marks a significant milestone in addressing the challenges faced by healthcare systems,” said Angelo Rago, President of Luminex. *“The LIAISON NES[®] system empowers clinicians with rapid, reliable results that support a test-and-treat approach, enabling timely, informed decisions that improve patient care and help curb the spread of respiratory infections.”*

This development reinforces Diasorin’s strategy to deliver a comprehensive molecular diagnostics ecosystem that enables effective Diagnostic Stewardship, providing the diagnostics tools to offer the right tests, for the right patient, at the right time, ultimately leading to more accurate diagnoses, better patient outcomes, and more efficient use of healthcare resources¹. The company’s molecular offering ranges from targeted solutions on the LIAISON[®] MDX, featuring several *De Novo* FDA-authorized specialty assays, to multiplex capabilities on the LIAISON PLEX[®], the first fully customizable syndromic molecular platform on the market, and the MAGPIX[®] platform for high-throughput syndromic testing. This integrated portfolio supports a broad spectrum of diagnostic needs, from centralized lab testing to rapid, near-patient diagnostics.

“The future of diagnostic testing lies in addressing real-world challenges,” said Carlo Rosa, CEO of Diasorin. *“As leaders in diagnostics, we remain steadfast in our commitment to innovation, delivering solutions that empower healthcare systems to maintain and elevate patient care, even amid cost pressures and resource constraints. The LIAISON NES[®] submission to the FDA aligns with the strategic priorities outlined at our 2023 Investor Day and marks another significant milestone in our path to enter the near-patient molecular diagnostics space, matching emerging medical needs”.*

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About Diasorin

Headquartered in Italy and listed at the Italian Stock Exchange in the FTSE MIB Index, DiaSorin is a global leader in the In Vitro Diagnostic (IVD) field and is active since 2021 in the Life Science business. For over 50 years, the Company has been developing, producing and marketing reagent kits used by diagnostic laboratories worldwide.

The Group operates in 5 continents through 34 companies, 4 branches, 10 manufacturing facilities and 9 research and development centers. The extensive diagnostic testing and Life Science offer, made available through continuous investments in research, positions DiaSorin as the player with the broadest range of specialty tests available within the diagnostic market, and identifies the Group as the "Diagnostic Specialist".

More info at www.diasorin.com

FOR ADDITIONAL INFORMATION, PLEASE CONTACT:

INVESTOR RELATIONS

Riccardo Fava

Corporate VP Communication, ESG & Investor Relations
riccardo.fava@diasorin.com

Eugenia Ragazzo

Corporate Investor Relations & ESG Analyst
eugenia.ragazzo@diasorin.com