PRESS RELEASE

DIASORIN RECEIVES CE CERTIFICATION UNDER IVDR FOR THE LIAISON PLEX GASTROINTESTINAL *FLEX* ASSAY, EXPANDING CUSTOMIZABLE SYNDROMIC TESTING TO EUROPE

THE LIAISON PLEX GASTROINTESTINAL *FLEX* ASSAY:

- RECEIVES CE CERTIFICATION UNDER THE EUROPEAN IN VITRO DIAGNOSTIC MEDICAL DEVICES REGULATION (IVDR), ENABLING DIASORIN TO INTRODUCE ITS LIAISON PLEX FLEX TESTING APPROACH TO THE EUROPEAN MARKET;
- JOINS THE CE-CERTIFIED LIAISON PLEX RESPIRATORY *FLEX* ASSAY, CREATING A PORTFOLIO OF CUSTOMIZABLE SYNDROMIC TESTS FOR RESPIRATORY AND GASTROINTESTINAL INFECTIONS;
- BRINGS A NEW APPROACH TO SYNDROMIC TESTING, ALLOWING LABORATORIES TO ALIGN TESTING WITH THE PATIENT'S CLINICAL SCENARIO AND HELP REDUCE REPEATED, UNNECESSARY OR OVERLY BROAD TESTING ASSOCIATED WITH FIXED "ONE-SIZE-FITS-ALL" PANELS.

Saluggia, Italy – 9 November 2026 - Diasorin (DIA.MI) announced today that the LIAISON PLEX Gastrointestinal *Flex* Assay has received CE certification under the European In Vitro Diagnostic Medical Devices Regulation (IVDR). Together with the LIAISON PLEX Respiratory *Flex* Assay, Diasorin can now bring to the European market its customizable syndromic approach designed to move beyond the traditional fixed-panel approach.

The LIAISON PLEX Gastrointestinal *Flex* Assay is a sample-to-answer multiplex molecular test capable of detecting up to 24 gastrointestinal pathogen targets, including bacterial, viral, and parasitic pathogens. Using Diasorin's proprietary *Flex* Software, laboratories can tailor testing to the patient's clinical presentation and other relevant factors, including seasonality, clinical guidelines, travel history and immune status.

The LIAISON PLEX Gastrointestinal *Flex* Assay complements the LIAISON PLEX Respiratory *Flex* Assay, recently also CE Certified under IVDR, which detects up to 19 bacterial and viral respiratory targets in a customizable fashion. Both assays run on the LIAISON PLEX System, Diasorin's next-generation, automated, sample-to-answer molecular diagnostic platform designed for customizable syndromic testing.

With both the Gastrointestinal *Flex* and Respiratory *Flex* assays now IVDR CE certified, Diasorin intends to introduce in Q1 2027 its *Flex* Testing approach to European laboratories across two of the most important areas of syndromic infectious disease testing. The two assays are designed to give laboratories the breadth of a comprehensive syndromic panel while preserving the ability to select, analyze and report only the targets that are clinically appropriate for each testing algorithm or patient scenario.

*"Healthcare systems are asking diagnostics to deliver more clinical value while using resources more appropri*ately," said Angelo Rago, President of Luminex. "*With the IVDR CE certification of our Gastrointestinal Flex Assay, together with our Respiratory Flex Assay, we are bringing European laboratories a fundamentally different approach to syndromic testing: the breadth of multiplex testing with the flexibility to adapt the test to the patient and the*

clinical question. We believe this can help reduce unnecessary and repeated testing and associated cost, support diagnostic stewardship and contribute to more sustainable healthcare delivery."

About Diasorin

Headquartered in Italy and listed on Euronext Milan, 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 30 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

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