News Release

November 1, 2022

Eiken Chemical Co., Ltd.
Representative: Tsugunori Notomi, President & CEO
Securities code: 4549 [TSE Prime Market]

Eiken Chemical Launched the Fully Automated Faecal Immunochemical Test/Faecal Calprotectin Analyzer "OC-SENSOR Ceres™" [IVDR CE Marked]

Eiken Chemical Co., Ltd. [Headquarters: Taito-ku, Tokyo] announces that the Fully Automated Faecal Immunochemical Test/Faecal Calprotectin Analyzer "OC-SENSOR Ceres™" was released on 1st of November 2022, in compliance with the requirement for CE Marking stipulated in the In Vitro Diagnostic Regulation (EU) 2017/746.

This launch of OC-SENSOR Ceres™ ensures that laboratories in the European Union and other countries who rely on our OC-SENSOR series, faecal immunochemical test and faecal calprotectin test in their diagnostic workflows will be able to use these products seamlessly.

The OC-SENSOR Ceres™ is the successor to OC-SENSOR io™ and has inherited its compactness and excellent features providing easy operation, while accomplishing random access up to three measurement items such as haemoglobin and calprotectin in faeces using the existing dedicated stool collection devices, OC-Auto Sampling Bottle 3. OC-SENSOR Ceres™ achieves the analytical performance of the high-end model, OC-SENSOR PLEDIA™, in a local laboratory environment. Furthermore, usability has been enhanced with the additional functions such as barcode management of reagent lot and expiration dates, and automatic retest and dilution retest.

The EIKEN Group management philosophy is to protect the health of the public through health care services. Eiken Chemical has distributed its fully automated faecal immunochemical test analysers over 30 years, and OC-SENSOR series are currently used in more than 45 countries around the world. With the launch of OC-SENSOR series, we aim to further expand our business in the colorectal cancer screening and hospital market.

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About EIKEN

EIKEN CHEMICAL CO., LTD. was established in 1939 and was the first Japanese company that successfully developed and commercialised powdered culture media for microbiological investigations. The company has been recognised as a leader in the clinical diagnostics market and has a strong commitment to research and development toward innovative products and technologies that fulfil needs at global health issue. Please visit www.eiken.co.jp/en/ for more information.

About EU IVDR

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 IVDR regulation replaces the previous IVD directive, under which many Eiken's products have been CE marked, indicating IVDD compliance.