Fecal occult blood test reagents have obtained the EU's IVDR certification

Minaris Medical Co., Ltd. (President and Managing Director: Naoki Kanenari; hereinafter, "Minaris Medical") announces that its in vitro diagnostic reagents for fecal occult blood tests (hereinafter, "fecal occult blood tests reagents"), namely, "EXTEL HEMO・AUTO HS Latex," "EXTEL HEMO・AUTO Buffer," "EXTEL HEMO・AUTO HS Calibrator," and "EXTEL HEMO・AUTO HS Control," obtained certification of the In Vitro Diagnostics Medical Devices Regulation (hereinafter, "IVDR certification") of the European Union on March 8, 2022. These fecal occult blood test reagents have been developed for the use of cancer screening tests. By obtaining IVDR certification, the safety and efficacy of Minaris Medical's reagents used for colorectal cancer screening tests have been reconfirmed.

IVDR certification is given to products or organizations that conform to the IVDR. Certifying bodies authorized by the European Commission, the executive branch of the European Union, examine the quality management and control systems and technical documents of the products or organizations, and issue certificates when confirmed as compliant with the regulation. The IVDR replaces the current In Vitro Diagnostic Directive to strengthen the management of safety and efficacy In Vitro Diagnostic Directive. The IVDR was approved by the European Commission in May 2017 and its enforcement is scheduled to begin on May 26, 2022. Compared with conventional regulations, the IVDR can be applied to a wider range of in vitro diagnostic medical devices[*1] (hereinafter, "IVD medical devices") categorized into four risk classes from Class A (lowest risk) to Class D (highest risk) according their purpose. IVD medical devices used for fecal occult blood tests in cancer screening fall into Class C. Manufacturers are required to strictly control the devices in line with the risk class. The IVDR will be enforced with a transition period set for each risk class. After the transition period, products cannot be sold in the EU market without IVDR certification.

Minaris Medical has been marketing fecal occult blood test reagents and their analyzers since 1996 when the company was its predecessor, Kyowa Medex Co., Ltd.. Today, the products are sold in Japan and also in European and Asian countries. With Minaris Medical's fecal occult blood test reagents obtaining IVDR certification, we aim to expand the marketing network further by offering products and services that satisfy increasingly diverse clinical needs to medical examination facilities and institutions.

In 1975, Minaris Medical commercialized Japan's first quantitative measurement reagent of total cholesterol that employs the enzyme reaction method.[*2] Since then, the company has been providing in vitro diagnostic reagents and analyzers for biochemical testing of dyslipidemia and diabetes, immunological allergy tests, and other applications. Through the development of in vitro diagnostic reagents and analyzers that serve the needs of the times, we aim to contribute to advancing treatments of various diseases while enhancing patients' quality of life.

*1 In vitro diagnostic medical devices (IVD devices) : Any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens derived from the human body. (Source: IVDR (EU) 2017/746)

*2 Publication of patent application Showa 60-58959

[Outline of the Products]

Marketing names:

EXTEL HEMO・AUTO HS Latex

EXTEL HEMO・AUTO Buffer

EXTEL HEMO・AUTO HS Calibrator

EXTEL HEMO・AUTO HS Control

Purpose of use: Screening and diagnostic support of intestinal diseases, including colorectal cancer

Category: Class C

Date of IVDR certification: March 8, 2022