News Release

June 11, 2021
Sysmex Corporation

Sysmex Obtains IVDR Certification for LYNOAMP™ CK19 E, a Gene Amplification Detection Reagent

-Prompt response to legislative changes in the European region that demand greater product safety-

Sysmex Corporation (HQ: Kobe, Japan; Chairman and CEO: Hisashi Ietsugu) announced that the Company obtains the EU's *In Vitro* Diagnostic Medical Devices Regulation (IVDR)[1] certification, a first for one of our products, for the gene amplification detection reagent LYNOAMP CK19 E, which uses the OSNA™ method[2] developed by Sysmex as the measurement principle, from TÜV SÜD Product Service GmbH on June 4, 2021.

In the European region, the IVDR went into effect on May 26, 2017 to further improve the quality and safety of *in vitro* diagnostic medical devices. Manufacturers of *in vitro* diagnostic instruments and reagents are required to obtain certification based on an examination by a notified body designated by the European regulatory authority and to display the CE mark accordingly, in order to market, sell, and distribute their products within the European Economic Area.

With the aim of stably supplying products and services to its customers, Sysmex has been working with its European subsidiaries to rapidly respond to these important revisions in regulations, and has been building a system to promptly obtain the CE mark in accordance with the IVDR. Sysmex has capitalized on its network with key opinion leaders (KOLs), built up through activities aimed at increasing the clinical value of cancer lymph node metastasis testing, and has established robust clinical evidence by acquiring basic data and documenting the results of joint research.

On June 4, 2021, Sysmex acquired IVDR certification in Europe from the notified body TÜV SÜD Product Service GmbH for LYNOAMP CK19 E, a gene amplification detection reagent for the European market, as a Class C *in vitro* diagnostic medical device.

Sysmex has identified the "provision of responsible products and services" as materiality and is reinforcing its system to ensure the stable delivery of products and services to customers around the globe. Going forward, Sysmex will continue to acquire IVDR certification for the IVD products that the company provides across Europe in catering to various fields, and to contribute to human health by stably providing high-quality, high-value-added products to customers around the world.

Product Overview

Brand name:	LYNOAMP™ CK19 E
Classification:	Class C
Target market:	Europe
Approval obtained:	June 4, 2021
Intended purpose:	LYNOAMP CK19 E is an *in vitro* diagnostic reagent kit for detection and quantification of CK19 mRNA in surgically removed lymph

node(s) lysate of breast, colorectal and gastric cancer patients as an aid to diagnosing the size of metastasis and metastatic burden in the lymph node(s). LYNOAMP CK19 E is intended for use on the Sysmex Gene Amplification Detectors. It shall be used by healthcare professionals and properly trained personnel.

Reference

Press release dated May 10, 2018: “Sysmex Launches New Products in Its System for the Testing of Cancer Lymph Node Metastasis Using the OSNA™ Method: Gene Amplification Detector RD-200 and LYNOAMP™ CK19”
https://www.sysmex.co.jp/en/news/2018/180510.html

Notes

1 *In Vitro* Diagnostic Medical Devices Regulation (IVDR):
Also referred to as Regulation (EU) 2017/746, the IVDR is a new legal regulation that applies to the marketing, sales, and distribution of *in vitro* diagnostic medical devices in the European market. The IVDR entered into force on May 26, 2017, repealing the current European Directive on *in vitro* diagnostic medical devices (98/79/EC). The transition period runs through May 26, 2022. It is divided into four classes, with class A as the lowest risk and class D the highest risk.

2 OSNA method:
Abbreviation of the One-Step Nucleic Acid Amplification method, developed by Sysmex, which enables detection of lymph node metastasis.