News Release

Sysmex obtains the first IVDR certification for LYNOAMP ™ CK19 E, a Gene Amplification Detection Reagent

Norderstedt, Germany, 16 June 2021 – Sysmex Europe GmbH announced today that LYNOAMP CK19 E [1], part of OSNA™ [2] method using a molecular biological technique for cancer diagnostics, is the first Sysmex product to be certified by a notified body under the new European *In Vitro* Diagnostic Medical Devices Regulation (IVDR) [3] on 4 June 2021.

IVDR demands greater clinical evidence and a more stringent review of technical documentation and supporting evidence. Manufacturers of *in vitro* diagnostic medical devices are obliged under IVDR to obtain a notified body certification of the technical documentation and quality management system for their devices.

Since IVDR enforcement in May 2017, Sysmex has been working tirelessly to rapidly respond to the new regulation and to promptly obtain the IVDR certification for its products. The efforts are recognised with this first major milestone when the company acquired IVDR certification in Europe from the notified body TÜV SÜD Product Service GmbH for LYNOAMP CK19 E as a risk class C *in vitro* diagnostic medical device.

“This is a significant achievement for Sysmex and confirms our position as front-runners in the IVD industry with our prompt response to the latest changes in the European regulatory landscape,” says Alain Baverel, President & CEO at Sysmex Europe.

“The level of scrutiny that a risk class C, IVD product such as LYNOAMP CK19 E is under is enormous. The biggest step is taken, and we have paved the way,” continues Samantha Giangregorio, Vice President Life Science at Sysmex Europe.

Going forward, Sysmex confirms its commitment and diligence in acquiring IVDR-mandated certification for required IVD products in the European market, and to continue to contribute to healthcare by providing high-quality, high-medical-value products to customers.

About Sysmex Europe GmbH

Sysmex supports healthcare professionals around the world in lighting the way with diagnostics by providing a broad range of medical diagnostics products and solutions. In the fields of haematology, urinalysis, haemostasis, life science, flow cytometry, essential healthcare and now immunochemistry, we combine highly dependable, multi-functional and easy-to-operate instruments, a variety of reagents and software, plus reliable service and support.

Sysmex Europe GmbH, located near Hamburg, Germany, is a subsidiary of the Sysmex Corporation from Kobe, Japan. From our Hamburg offices, we serve our affiliates, distributors and customers throughout Europe, the Middle East, and Africa (EMEA). For more information, visit www.sysmex-europe.com.

References

1. LYNOAMP CK19 E:
   In vitro diagnostic reagent kit for quantification of CK19 mRNA in surgically removed lymph node(s) lysate of breast, colorectal and gastric cancer patients.
2. OSNA:

   Abbreviation for One-Step Nucleic Acid Amplification. An *in vitro* diagnostic test of metastasis size and metastatic tumour burden in the lymph node(s) of cancer patients.

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3. *In Vitro* Diagnostic Medical Devices Regulation (IVDR):

   Also referred to as Regulation (EU) 2017/746, the IVDR is the new EU regulation that applied to the marketing, sales and distribution of in vitro diagnostic medical devices and accessories for human use in the European market.