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Sysmex Corporation

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## Sysmex Obtains First Marketing Approval in Japan for the Automated Hematology Analyzer XN-31 as a Class III Specially Controlled Medical Device to Diagnose Malaria

- For Use as a Measure against Imported Infectious Diseases in Japan and Accelerating its Introduction to the Asian and African Markets -

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Sysmex Corporation (HQ: Kobe, Japan; Chairman and CEO: Hisashi Ietsugu) announced today that it has obtained a medical device marketing authorization ("marketing approval") for its Automated Hematology Analyzer XN-31 as a Specially Controlled Medical Device for use in the diagnosis of malaria (Class III)<sup>1</sup> for the first time in Japan. With this, it is now possible to use this analyzer for clinical use as a measure against imported infectious diseases in Japan.

Now that marketing approval has been received in Japan, we will accelerate our move to obtain marketing approval in other countries in Asia and countries in Africa, thus contributing to global efforts to eliminate malaria.

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Identified as one of the world's three major infectious diseases by the World Health Organization (WHO), malaria is a protozoal disease resulting from plasmodia transmitted by mosquitoes, and is prevalent in tropical and sub-tropical regions around the world. When malarial parasites enter a person's body, circulating red blood cells (RBCs) are infected after a certain incubation period, and the patient begins to exhibit symptoms such as high fever, headache, vomiting, and anemia. According to the World Malaria Report 2019 by the WHO, approximately 4.0 billion persons, or about half of the world population, are at risk of malaria; approximately 230 million persons were infected by it in 2018, and an estimated 410,000 persons died from it in the same year. The report also stated that every year at least 30,000 persons, either on vacation or business, get infected by malaria at their destinations, including non-epidemic areas, and diagnosed the disease after they return home. Japan is no exception to this, and more than 50 such cases are reported annually, although malaria has been formally eradicated in this country. Because delay in diagnosis and treatment can lead to a worsening of symptoms, early diagnosis<sup>2</sup> and efficient and standardized<sup>3</sup> testing of malaria are of great importance.

We have identified the "resolution of medical issues through products and services" as one of the priority issues for realizing a sustainable society and sustainable growth for Sysmex. As one aspect of this approach, we aim to contribute to the early detection and treatment of malaria by supporting improved efficiency and standardization of malaria testing throughout the world.

On June 26, 2020, Sysmex obtained marketing approval in Japan for the Automated Hematology Analyzer XN-31, for which a CE certification indicating that the product complies with the European IVD Directive had been obtained in April 2019, making this product the first medical device for *in vitro* diagnosis approved in Japan as a Specially Controlled Medical Device for use in the diagnosis of

malaria (Class III). Early diagnosis and treatment of malaria can reduce the number of deaths among those who contract it. Through this product, which is capable of providing quick and easy testing results useful in diagnosis in clinical settings, Sysmex wishes to contribute to measures against imported infectious diseases in Japan. Now that we have received marketing approval, we are planning to have this technology approved by regulatory authorities in selected countries in Asia and Africa to accelerate its market introduction there.

Domestic marketing approval as a medical device with high-level control is required in the procurement criteria<sup>4</sup> of international funds and funding from other organizations which work to improve access to healthcare in emerging and developing countries. Through partnerships with such organizations, we aim to introduce the product to countries and regions, either emerging or developing, where medical resources are limited.

Going forward, Sysmex will continue working to resolve medical issues through business activities and promote efforts that improve access to healthcare. We will continue to inspire trust and confidence among our customers in developing countries and all over the world.

#### **Product Overview**

Generic name:	Malaria diagnostic device (71081003), Automated hematology analyzer (35476000)
Name:	Automated Hematology Analyzer XN-31 (Medical Device Marketing Authorization Number: 30200BZX00211000)
Classification:	Class III
Intended use:	This automated hematology analyzer aids the diagnosis of malaria by making qualitative analyses of formed elements in whole blood based on the count of DNA-containing malaria-infected RBCs (MI-RBCs) that contain such as malaria parasites, by way of electric impedance, light scattering by irradiating laser light onto cells that move inside the flow cell, or dye binding. It also counts, quantitates, and identifies platelets, RBCs, and white blood cells, measures hemoglobin, and determines hematocrit values, corpuscular constant, RBC distribution width (RDW), platelet distribution width (PDW), mean platelet volume (MPV), plateletcrit (PCT), and large platelet fraction.
Launch:	The end of August 2020
Manufacture and sale:	Sysmex Corporation

#### **Reference**

April 25, 2019 press release entitled “Sysmex Obtains CE Certification for Automated Hematology Analyzer XN-31, Which Has an Automatic Measurement Function for Red Blood Cells Infected by Malaria Parasites -Contributing to the Early Detection and Treatment of Malaria through Standardized and More Efficient Malaria Testing-”  
<https://www.sysmex.co.jp/en/news/2019/190425.html>

## Terminology

- 1 Specially Controlled Medical Device (Class III):  
A medical device whose failure is deemed to pose a relatively high risk to health.
  
- 2 Importance of early diagnosis of malaria:  
Partly because malaria had been eradicated in Japan, there are cases where malaria is not suspected and is misdiagnosed as a different disease, or a delay in diagnosis or treatment occurs as malaria testing is not done promptly. Early diagnosis is particularly crucial for tropical malaria because it can become severe if not treated within 24 hours of onset.
  
- 3 Importance of increasing the efficiency of, and standardization of, malaria testing:  
Current malaria testing uses a microscope or rapid diagnostic test kits. Both methods require around 15-30 minutes, including manual sample preparation, making it difficult to conduct a large number of tests at once. In addition, because microscope testing is largely dependent on the skills of technicians, standardizing malaria testing by, for example, training technicians and systematically assuring the quality of testing and securing a stable source of skilled technicians, are an ongoing issue.
  
- 4 Procurement criteria of international funds and other organizations:  
The WHO and international funds permit a simplified examination process for high-risk products if those products have obtained approval from a rigorous examination body that those organizations designate, with a view toward accelerating the introduction of various products to emerging countries and developing countries. This is stated in their procurement criteria, and regulatory approval as a Specially Controlled Medical Device (Class III) in Japan qualifies as one of these rigorous examination criteria.