



May 17, 2022

Software as Medical Device (SaMD) Approval Support Achievements

Micron, Inc. (Head Office: Tokyo, President: Michita Sato), a subsidiary of CE Holdings Co., Ltd. (Tokyo Stock Exchange – TSE, Prime Section) which provides support services for medical imaging technology and clinical trials., is pleased to announce that research conducted by Micron of SaMD approvals*¹ in Japan showed that as of December 31, 2021, there were 30 approved software programs for disease diagnosis in the controlled medical device category in Japan, 8 of which (more than 25%) were supported by Micron.

Micron, as a CRO supporting the development of pharmaceuticals and medical devices, provides development support services, and the manufacturing and sales of SaMD products. In particular, we have received many business inquiries from SaMD product developers not only in Japan, but also from overseas for our development support services, and as of the end of March 2022 we had assisted 29 SaMD products in obtaining approvals and certifications, including those that are still ongoing.

Currently, we are receiving an increasing number of inquiries regarding the development of disease treatment software in addition to disease diagnosis software. We're excited to support SaMD products other than diagnostic imaging as well in the near future.

Examples of SaMD Products Micron Supported

Generic Name	Classification	Modality	Target Disease
Software intended for disease diagnosis	Controlled medical device	CT	COVID-19
Software intended for disease diagnosis	Controlled medical device	Echography	Breast cancer
Software intended for disease diagnosis	Controlled medical device	Endoscope	Colorectal cancer

The number of developments of SaMD products is expected to increase more and more, and the number of support cases and consultations for selling SaMD products that have been approved and certified overseas are also increasing.

Micron will make use of its experience to support the development of SaMD products, and will seek

to generate synergies in the CRO business.

***1 Approval of SaMD**

Advanced, high-risk medical devices are "approved (shonin-承認)" by the Ministry of Health, Labor and Welfare (MHLW) minister after review by the Pharmaceuticals and Medical Devices Agency (PMDA). For those with relatively low risk and certification standards, a registered certification body will "certify (ninsho – 認証)" that the requirements have been met. Of course, Micron also assists in obtaining certifications.

Micron, Inc. Company Information

Head Office	3-13-16 Mita, Minato-ku, Tokyo, Japan
Business Contents	<ul style="list-style-type: none">- Supports the development of pharmaceuticals, diagnostics, medical devices, biomarkers, and AI guided SaMD by utilizing imaging technologies- Clinical development support (monitoring, quality control, imaging core lab, image analysis, central imaging review, etc.)- PET tracer manufacturing support- Consulting for clinical development- Second-class marketing license for medical devices- ICCC services
URL	https://micron-kobe.com/

Contact

Micron, Inc. Sales and Marketing Department

E-mail	info@micron-kobe.com
--------	----------------------