



October 4th, 2022

Software as a Medical Device Licensing in Taiwan

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 it has completed medical device registration (Class II medical device) in Taiwan, and obtained a license from the Taiwan Food and Drug Administration (TFDA) for PMAneo brain imaging analysis software.

Product Name	“邁科隆” 醫學圖像分析軟體 “Micron” PMAneo Medical Images Analysis Software
License Number	035782
Manufacturer	Manufactured by Liberworks Co., Ltd. for Micron Inc.

PMAneo is an application that uses MRI diffusion-weighted imaging (DWI)/MR perfusion imaging (PWI) or CT perfusion imaging (CTP) to provide information for treatment decisions, evaluations, or diagnoses related to clinical conditions. This fully automated brain image analysis software measures low ADC value areas from DWI, and computes CBF, CBV, and Tmax from PWI or CTP. It also calculates and displays the volume of cerebral hypoperfusion areas and the mismatch volume and ratio between them.

In recent years, in the field of medical imaging, there have been many efforts to automatically process image data, calculate quantitative values, and utilize these values as indicators (imaging biomarkers) of clinical conditions and therapeutic effects. This is a part of such efforts, and this software will be provided to medical institutions nationwide through distributors.

Micron, as a CRO supporting the development of pharmaceuticals and medical devices, provides development support services, and the manufacturing and sales of SaMD (Software as a Medical Device) products. In particular, as of the end of March 2022 we had assisted over 20 SaMD products in obtaining approvals and certifications, including those that are still ongoing.

We are preparing to expand sales of SaMD products in the global market in order to globally develop medical devices originating from Japan in the future with the support of JETRO (Japan External Trade Organization). As a first step, we have obtained the medical device certification under the medical

device application system in Taiwan.

Micron also provides sales support for SaMD products to foreign companies seeking sales channels in Japan.

Micron will use its experience to support the development of SaMD products, and will seek to generate synergies in the CRO business.

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
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