

Notice of approval for First-Class Marketing License for Medical Devices

Tokyo, Japan – December 22, 2023 - Medical and Biological Laboratories Co., Ltd. (CEO: Hiroki Ito, “MBL”), a JSR Life Sciences Company, announces that it has obtained a First-Class Marketing License for Medical Devices in preparation for regulatory approval of NGS (next-generation sequencing)-based IVD products.

Categories of Permit: First-Class Marketing License for Medical Device

License number: 20B1X10007

Date of license acquisition: November 24, 2023

With the acquisition of the First-Class Marketing License for Medical Devices, MBL will be able to market highly controlled medical devices, including genetic testing systems using NGS. MBL will continue to develop advanced and innovative IVD products and contribute to the development of health and medical care.

* What is a first-class marketing license for medical devices?

The Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices establishes various legal regulations at each stage of research and development, manufacturing and marketing, distribution, and post-marketing to ensure the quality, efficacy, and safety of pharmaceuticals and medical devices. The marketing of pharmaceuticals and medical devices is subject to registration and approval by the Ministry of Health, Labour and Welfare and prefectural governments. Medical devices are classified into classes, from Class I to Class IV, according to their intended use and the level of potential risk. The First-Class Marketing License for Medical Device is the highest level of authorization, which allows the handling of all medical devices from Class I to Class IV.

Contact:

Medical and Biological Laboratories Co., Ltd.

Molecular Diagnostics Business Planning Department

Head Quarters: SUMITOMO FUDOSAN SHIBADAIMON NICHOME BLDG. 2-11-8 Shibadaimon,
Minato-ku, Tokyo 105-0012 Japan

Tel: +81-3-6684-6860

Contact form: <https://www.mblbio.com/e/contact/>

About Medical and Biological Laboratories Co., Ltd.

MBL was established in 1969 as the first antibody manufacturer in Japan, and researches, develops, manufactures, and sells reagents of in vitro diagnostics and reagents for basic research. MBL has now expanded its business not only to the immunological field but also to the field of genetic diagnosis. In the field of oncology, MBL is contributing to personalized medicine by developing companion diagnostics. For more information, please visit <https://www.mblbio.com/cdx/>.