



FDA Medical Device Conformity Assessment and Certification Program (ASCA)

2 March 2023

## TÜV SÜD Japan Tokyo Testing Centre accredited as FDA ASCA accredited Laboratory

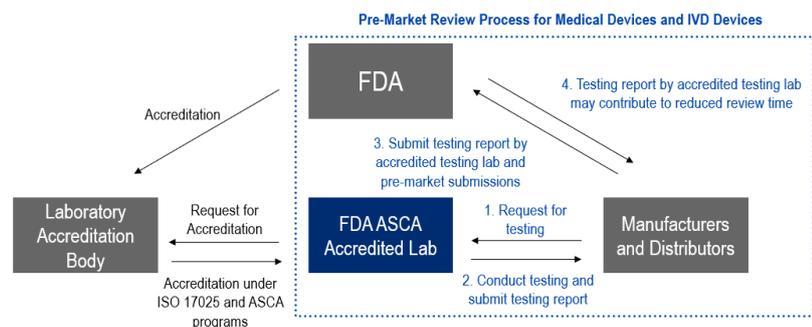
**Tokyo. Tokyo Testing Centre of TÜV SÜD Japan, local subsidiary of TÜV SÜD – a globally acclaimed German safety and quality expert –, has been accredited as the Food and Drug Administration (FDA) ASCA Accreditation Laboratory. This accreditation indicates that laboratories are based on ISO 17025 and the FDA's Device Conformity Assessment Certification Program standards. Manufacturers and distributors of medical devices may contribute to reducing the time to approval by using the FDA ASCA-accredited laboratory. TÜV SÜD Japan Tokyo Testing Centre supports the largest number of standards of any accredited laboratory in Japan (as of February 2023).**

In order to manufacture and sell medical devices, including in vitro diagnostic products (IVDs), it is necessary to meet international regulations and standards. The requirements differ from country to country, and TÜV SÜD Japan provides testing and certification services as well as training services to meet these regulations.

In recent years, the number of applications for authorization of medical devices has been increasing, and the rationalization of the screening process has become an issue. In light of this situation, the “FDA Medical Device Conformity Assessment and Certification Program (ASCA)” emerged from discussions between FDA and medical device manufacturers. This program is designed to streamline the process without compromising the quality of pre-marketing reviews of medical devices and IVD devices. It is expected that this program will reduce the burden on the marketing authorisation holder by ensuring uniformity of data and information related to the study and increasing reliability of the study reports.



Figure : FDA ASCA program



TÜV SÜD Japan Tokyo Testing Centre

(TTC) has been accredited as an FDA ASCA Accredited Laboratory. This certification indicates that the TÜV

SÜD Japan TTC is based on ISO 17025 and the FDA's Medical Device Conformity Assessment Program (ASCA). Manufacturers and distributors of medical devices may contribute to reducing the time to approval and the likelihood of delay by conducting tests at FDA ASCA-approved laboratories and submitting an application for approval with the test report (see figure).

TÜV SÜD Japan received this accreditation from A2LA, the fourth among the TÜV SÜD Group's global medical device-related services, following the United States, Canada and Singapore: [ASCA-Accredited Testing Laboratories](#). In addition, TÜV SÜD Japan Tokyo Testing Centre supports the largest number of standards of any accredited laboratory in Japan (as of February 2023).

In the future, we will continue to provide testing and certification services that support compliance with laws and regulations by domestic medical device manufacturers and distributors.

### About TÜV SÜD Japan Tokyo Testing Centre

Tokyo Testing Centre is a laboratory of TÜV SÜD Japan, a Notified Body that has the ability to respond to almost all existing EU directives and is first registered with the Ministry of Health, Labour and Welfare in Japan. With ISO 17025 certification, it is possible to provide high-quality, wide-ranging tests.

- Address: 4F, NF Park Bldg., 2-9-15 Futaba, Shinagawa-ku, Tokyo 142-0043 Japan
- Scope of FDA ASCA program:



TL-116

TÜV SÜD Japan Ltd. Tokyo Testing Center

Basic safety and  
essential performance

Japan

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#### Current Scope of ASCA Accreditation

ANSI AAMI ES60601-1\*

IEC 60601-1-6

IEC 60601-1-8

IEC 60601-1-11\*

IEC 60601-2-5

IEC 60601-2-16\*

IEC 60601-2-18

IEC 60601-2-19\*

IEC 60601-2-20\*

IEC 60601-2-21\*

IEC 60601-2-22

IEC 60601-2-25\*

IEC 60601-2-27\*

IEC 60601-2-37\*

IEC 60601-2-47

IEC 80601-2-60

ISO 80601-2-74\*

IEC 61010-1\*

Click here for details: [ASCA-Accredited Testing Laboratories](#)

More information about TÜV SÜD Japan's medical device-related services: <https://www.tuvsud.com/ja-jp/industries/healthcare-and-medical-devices>

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Founded in 1866 as a steam boiler inspection association, the TÜV SÜD Group has evolved into a global enterprise. More than 25,000 employees work at over 1,000 locations in about 50 countries to continually improve technology, systems and expertise. They contribute significantly to making technical innovations such as Industry 4.0, autonomous driving and renewable energy safe and reliable. [www.tuvsud.com](http://www.tuvsud.com)