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Press Release

TÜV SÜD certifies Medicaroid's hinotori™ Surgical Robot System in accordance with the EU MDR

September 15, 2026

Local expertise in Japan and a global certification network enable successful MDR certification for the European market

Tokyo/Japan. TÜV SÜD Japan Ltd., in collaboration with TÜV SÜD Product Service GmbH, has successfully completed MDR certification of the hinotori™ Surgical Robot System developed by Medicaroid Corporation (Headquarters: Kobe, Hyogo Prefecture; Board Director, CEO and President: Koji Muneto). TÜV SÜD Product Service GmbH, acting as a Notified Body under the MDR, issued the EU certificate. As part of the certification process, TÜV SÜD Japan's local team of experts – comprising MDR auditors and qualified technical documentation assessors – carried out on-site audits and undertook part of the assessment of the technical documentation for the surgical robot system. To mark the successful certification, TÜV SÜD Japan and Medicaroid held a certification ceremony.



Medical devices must comply with the applicable regulations of each country or region in which they are marketed. In the EU, the Medical Device Regulation (MDR) establishes requirements intended to ensure the safety, performance and quality of medical devices. Once a notified body* has verified compliance with MDR requirements, an EU certificate is issued, allowing the product to bear the CE marking and be placed on the European market.

For Japanese manufacturers seeking to expand into the European market, achieving MDR compliance is an important milestone. MDR conformity assessment requires expertise in a broad range of activities, including quality management system assessments, technical documentation reviews, on-site audits and product evaluations. However, only a limited number of organizations in Japan are capable of conducting MDR audits and technical assessments in Japanese.

Recently, TÜV SÜD issued an EU certificate under the MDR for Medicaroid Corporation's hinotori™ Surgical Robot System. To celebrate this achievement, TÜV SÜD Japan and Medicaroid held a certification ceremony. The certification demonstrates Medicaroid's technological capabilities and its commitment to international expansion. During the ceremony, the company's further business growth in the European market was celebrated and anticipated.

The certificate was issued by TÜV SÜD Product Service GmbH in its role as a notified body under the MDR. As part of the certification process, TÜV SÜD Japan managed the project, conducting on-site audits and performing part of the technical documentation assessment of the surgical robotic system through its local expert team of MDR auditors and qualified technical documentation reviewers. Various safety tests and evaluations were also conducted at TÜV SÜD Japan's domestic testing laboratories.

The principal roles of the organizations involved in the project were as follows:

TÜV SÜD Japan Ltd. – Medical and Health Services (MHS) Division, Certification Management Department

- Conducted on-site audits covering manufacturing, design and sterilization processes, including audits at key suppliers.
- Performed assessments by technical documentation reviewers in Japan and overseas.
- Managed certification recommendations submitted to the notified body.
- Local experts also carried out part of the technical documentation review and assessment.

TÜV SÜD Japan Ltd. – Medical Testing Center (IEC/ISO 17025 Accredited)

- Conducted electrical safety testing, including IEC 80601-2-77 and related standards.
- Conducted functional safety testing.
- Conducted EMC testing.
- Conducted cybersecurity testing.

TÜV SÜD Product Service GmbH

- Served as the MDR notified body.
- Responsible for the final certification decision and issuance of the EU certificate.

TÜV SÜD Japan will continue to combine its local expertise in auditing and technical assessment with the global certification network of TÜV SÜD to provide practical support for the international expansion of innovative medical devices developed in Japan.

Further information on TÜV SÜD Japan's medical device services is available at:

tuvsud.com/ja-jp/industries/healthcare-and-medical-devices/medical-devices-and-ivd/medical-device-market-approval-and-certification/medical-device-regulation

From left to right:

Koji Muneto, Board Director, CEO and President of Medcaroid Corporation; Andrea Coscia, Representative Director and President of TÜV SÜD Japan Ltd.

About Notified Bodies

A notified body is an organization designated by a competent authority to carry out conformity assessments under applicable regulations. TÜV SÜD Product Service GmbH has been designated by the German authority ZLG as a notified body for conformity assessments under MDR.

*hinotori is a trade mark of Medcaroid Corporation.

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About TÜV SÜD Japan

Established in 1993 as the Japanese subsidiary of TÜV SÜD – a globally acclaimed German safety and quality expert with over 150 years of history. Through testing, certification, auditing and training services, TÜV SÜD Japan supports the safety and overseas expansion of companies in a wide range of industry fields, including medical devices, industrial equipment, consumer products, automotive, food, chemicals and energy. In recent years, TÜV SÜD Japan has also focused on cybersecurity, sustainability and AI-related services. tuvsud.com/ja-jp

About TÜV SÜD

Founded in 1866 as a steam boiler inspection association, the TÜV SÜD Group has evolved into a global enterprise. More than 30,000 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. tuvsud.com