

Korean startup AITRICS obtains medical device approval in Malaysia

May 19, 2026 | News

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AITRICS, a medical artificial intelligence (AI) startup in South Korea, has obtained medical device approval from the Medical Device Authority(MDA) of Malaysia for its AI solution for patient deterioration prediction, AITRICS-VC(VitalCare).

AITRICS-VC(VitalCare) is a medical AI solution that leverages electronic medical record (EMR) data from hospitals to predict patient deterioration at an early stage. This marks the sixth regulatory approval for AITRICS-VC(VitalCare), including Korea, further strengthening the company's foundation for global market expansion, including Southeast Asia, following its approval in Indonesia last month.

The approval obtained in Malaysia falls under Class C according to Malaysia's medical device classification system and was granted following a rigorous review of safety and effectiveness.

Malaysia is expanding the use of healthcare data and the digital transformation of hospital systems based on its national digital health policies. In particular, the Ministry of Health Malaysia is gradually building healthcare data infrastructure, including electronic medical records (EMR), electronic lifetime health records (ELHR), and a health information exchange (HIE), based on the national healthcare policy document Health White Paper, announced in 2023.

As the foundation for healthcare data utilisation continues to expand, the potential use of medical AI solutions that help identify high-risk patients at an early stage and support rapid responses by healthcare professionals is also growing.

Against this policy backdrop, AITRICS expects this approval to allow AITRICS-VC(VitalCare) to contribute to strengthening patient safety management systems in Malaysian healthcare settings.