

SGS awards Yaoshi the world's first IEC 81001-5-1 CB certification for medical device cybersecurity

SGS supports Yaoshi in achieving the world's first IEC 81001-5-1 CB certification for cybersecurity in a medical device

BAAR, SWITZERLAND, July 1, 2026 /EINPresswire.com/ -- SGS awards Yaoshi the world's first IECEE

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Gavin Yin, Connectivity & Products, SGS

CB certification in accordance with IEC 81001-5-1:2021 for its ultra-widefield scanning laser ophthalmoscope (SLO) following a comprehensive assessment and conformity verification process.

A provider of advanced ophthalmic imaging technology, Yaoshi reached this global milestone for its Yetsea 300 series. In addition to this cybersecurity certification, CB certifications for electrical safety and electromagnetic compatibility (EMC) were also issued, demonstrating SGS's comprehensive approach to compliance across safety, performance and cybersecurity.

IEC 81001-5-1 is an international standard that addresses cybersecurity throughout the life cycle of health software and IT systems, from design and development through testing and post-market activities. As the first application of this standard within the IECEE CB Scheme, this certification establishes a new benchmark for cybersecurity in medical devices.

SGS conducted a structured and comprehensive assessment program to evaluate Yaoshi's compliance with IEC 81001-5-1 requirements. At the product level, activities included threat modeling, risk assessment, penetration testing, vulnerability scanning, code auditing and software bill of materials (SBOM) review to identify potential risks.

At the system level, SGS assessed cybersecurity management processes and supporting documentation, verifying the integration of security practices across quality management, development, testing and post-market monitoring and response activities. By adopting an independent verification approach, SGS confirmed alignment with international cybersecurity, safety and performance requirements.

Gavin Yin, Director of Medical Devices Services, East China, Connectivity & Products, SGS: "This certification represents a significant step forward in addressing cybersecurity risks in connected medical devices. By combining expertise in cybersecurity, electrical safety and EMC, we support manufacturers in meeting evolving regulatory expectations and strengthening trust in healthcare technologies."

With cybersecurity now an essential component of regulatory compliance, the ability to demonstrate robust, life cycle-based security practices is increasingly important for enhancing safety, effectiveness and security of medical devices. The IECEE CB Scheme supports international acceptance of test results, reducing duplication and accelerating entry into key markets such as Europe, North America and Japan.

SGS continues to expand its global cybersecurity certification capabilities, supporting medical device manufacturers worldwide in addressing evolving requirements and strengthening trust in connected healthcare systems. With its global network of medical device experts and technological know-how, SGS is committed to delivering one-stop services covering product testing, auditing and certification.

SGS DIGITAL TRUST is a global framework that strengthens and consolidates SGS' services into a structured and consistent approach to help organizations navigate today's complex digital trust landscape with confidence. Built on proven expertise, [SGS DIGITAL TRUST: Across technologies, services and organizations](#) enables customers to build, demonstrate and sustain trust across the digital ecosystem.

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