

September 6th, 2019
Sanyo Chemical Industries, Ltd.

Sanyo Chemical obtains CE marking of innovative surgical sealant
—Non-bio-derived hemostatic material MATSUDAITO (overseas brand name: AQUABRID®) —

Sanyo Chemical Industries (Kyoto, Japan) announced today its certification of CE marking of cardiovascular hemostatic sealant, its brand name AQUABRID® in Europe by DEKRA. Sanyo Chemical is a mission-oriented company, always making unprecedented challenges. Its cardiovascular hemostatic sealant certified by DEKRA is classified as highest risk devices which are subject to most stringent scrutiny.

This certification marks Sanyo's first achievement in their European business. Since October in 2019, Sanyo Chemical will distribute AQUABRID® in corporation with Terumo Europe NV (Leuven, Belgium).

Takao Ando, President CEO at Sanyo Chemical said "Without DEKRA's hard work, we can never make this happen. Their effort to bring only patient-first product is admirable. DEKRA Japan provided timely assistance which was most appreciated for us".

DEKRA has rich professional knowledge and experience in the Medical field and is one of the five largest Notified Bodies in the world. DEKRA has already obtained Notified Body (NB) designation for European Medical Devices Regulation (MDR), NB number of DEKRA Certification GmbH is 0124.

Additionally it is expected to obtain MDR accreditation as well for DEKRA Certification B.V in Netherlands with Notified Body number 0344.

With a global network of offices and state-of-the-art laboratories, DEKRA can also help medical manufactures to gain worldwide access to markets including Europe, Taiwan, the USA, Canada, Brazil, Australia and Japan. In addition, DEKRA can provide certification support for quality management systems in combination with CE certification.

About Sanyo Chemical

Sanyo Chemical is a manufactures and sales of performance chemicals, established in 1949 in Kyoto. Performance chemicals featured by functional characteristics respond various needs such as more beautiful, safer, more comfortable and environment friendlier. We started as a manufacturer of soap and textile agents, and diversified our product line to satisfy the needs of the market. Our company operates in six business segments: toiletries & health, petroleum & automotive, plastic, textiles, info/electronic & construction/others. Our solutions are essential to our daily lives from automotive to daily electronics, passing by cosmetics and medical equipment. Now we have over 3,000 different types of products and an international presence. We endeavor to create better life and society through performance chemicals in various fields.

About DEKRA

DEKRA has been active in the field of safety for more than 90 years. Founded in 1925 in Berlin as Deutscher Kraftfahrzeug-Überwachungs-Verein e.V., it is today one of the world's leading expert organizations. DEKRA generated revenues totaling more than EUR3.3 billion in 2018. The company currently employs more than 45,000 people in around 60 countries on all six continents. With qualified and independent expert services, they work for safety on the road, at work and at home. These services include vehicle inspection, claims & expertise, product testing, industrial inspection, audits, consulting, training and temporary work. The vision for the company's 100th birthday in 2025 is that DEKRA will be the global partner for a safe world.



Picture of a CE marking certification award ceremony
From left Managing director,medical Kazuya Hijii and Representative director Miguel Delorme at DEKRA Certification Japan K.K.,
President & CEO Takao Ando and Managing director of Biotechnology & Medical Division Hideya Narutaki at Sanyo Chemical Industries, Ltd.