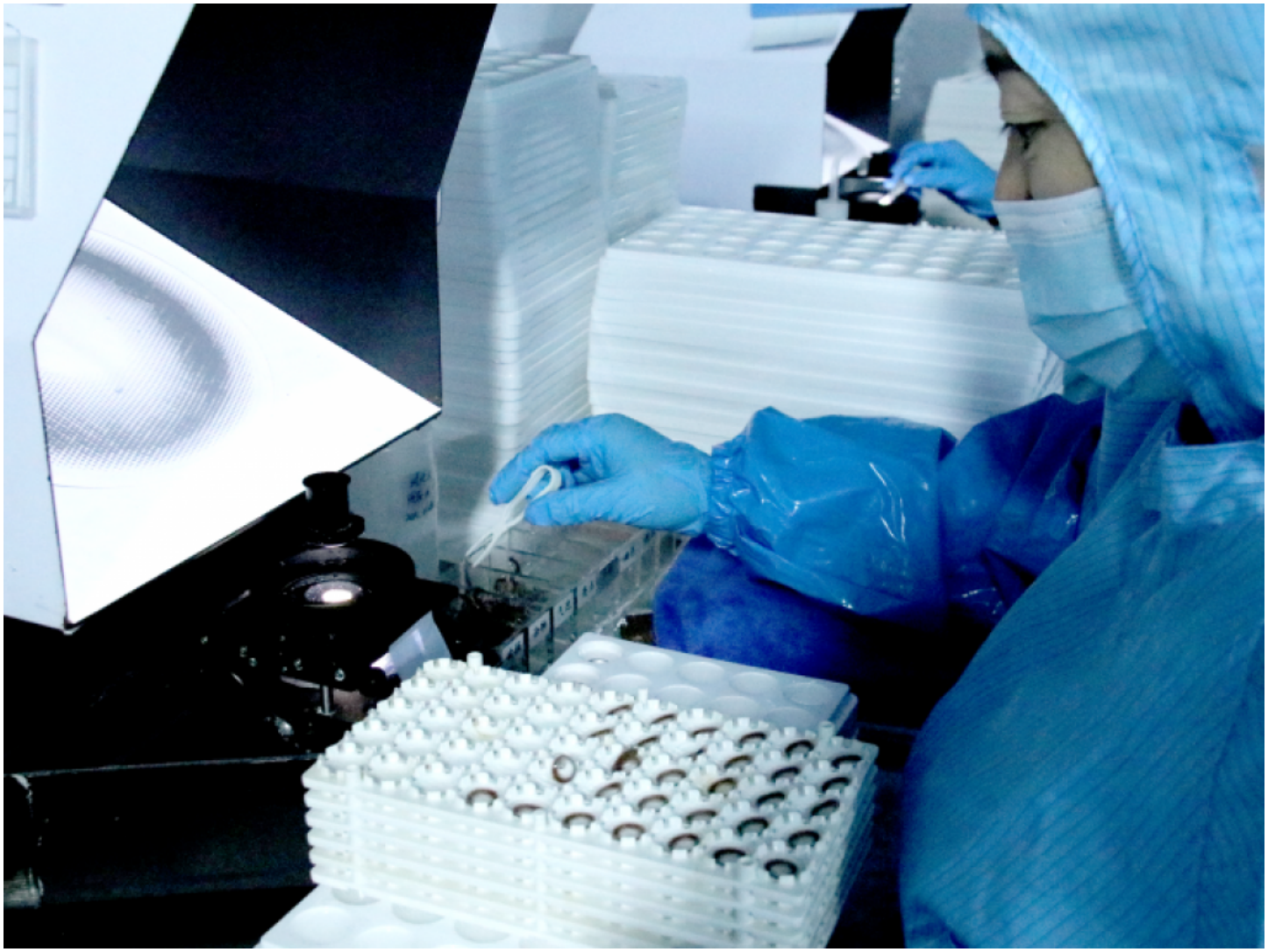
Constar Completes Eight-Market Regulatory Portfolio, the Only Contact Lens Manufacturer in China With FDA, CE and ISO



Baiyin, Gansu Sep 23, 2026 (Issuewire.com**)** - FDA 510(k) clearance, CE 0197 marking and ISO 13485 certification now sit alongside national registrations in Australia, Saudi Arabia, Indonesia, Thailand and Vietnam — a combination held by no other contact lens manufacturer in China

Gansu Constar Technology Group Co., Ltd. today confirmed that it holds market registrations across eight regulated contact lens markets, allowing brand owners and distributors to source from a single manufacturer for territories that would otherwise require separate supply relationships.

The portfolio combines three core certifications — US FDA 510(k) clearance, CE 0197 marking for the European Union, and ISO 13485 quality management registration — with five national market authorisations: TGA ARTG listing for Australia (2024), SFDA license for Saudi Arabia (2024), AKL Kemenkes permit for Indonesia (2024), TFDA license for Thailand (2023), and Class B registration for Vietnam (2024). The company additionally holds China NMPA medical device manufacturing and

business licences.

Constar is the only contact lens manufacturer in China holding FDA 510(k) clearance, CE 0197 marking and ISO 13485 certification simultaneously — a combination that allows a single quality system to serve the United States, the European Union and, through ISO 13485's international recognition, most other regulated markets.

Why the Portfolio Matters Now

The confirmation comes as regulators across Southeast Asia and the Middle East tighten registration requirements for contact lenses. A category once treated as a consumer cosmetic product is increasingly regulated as a medical device, with mandatory registration, technical documentation and post-market surveillance obligations in a growing number of markets.

For brand owners, that shift has a direct operational consequence. A manufacturer holding clearance in only one or two territories cannot serve a distributor whose sales footprint crosses borders. Sourcing from several factories to cover several markets means duplicating tooling, artwork, packaging lines, and quality audits — and managing separate documentation trails for each.

What the Three Core Certifications Cover

FDA Clearance — United States. Under US regulation, soft contact lenses intended for daily wear are Class II medical devices requiring 510(k) premarket notification before they can be marketed. Constar's clearance covers its soft contact lens range, including daily disposable, monthly, and coloured cosmetic designs. US importers can review the applicable requirements in the guide to importing contact lenses to the United States.

CE 0197 — European Union. CE marking under the EU Medical Device Regulation 2017/745 is mandatory for placing contact lenses on the European Economic Area market. The 0197 designation identifies the notified body that assessed the manufacturer's conformity, covering clinical evaluation, biocompatibility testing, and post-market surveillance obligations.

ISO 13485 — Global Quality Management. ISO 13485 is the international quality management standard specific to medical devices. It is not a market authorisation in itself, but it is a baseline requirement that most national regulators reference when assessing a manufacturer for local registration.

What the Five Regional Registrations Add

Australia — TGA ARTG listing, 2024. Therapeutic Goods Administration registration permitting supply to the Australian market.

Saudi Arabia — SFDA license, 2024. Approval from the Saudi Food and Drug Authority. Importers can review the registration pathway in the SFDA medical device registration guidance.

Indonesia — AKL Kemenkes permit, 2024. Medical device permit from the Indonesian Ministry of Health.

Thailand — TFDA license, 2023. Licensing from the Thailand Food and Drug Administration.

Vietnam — Class B registration, 2024. Medical device Class B registration for the Vietnamese market.

What This Changes for Brand Owners

The practical effect is supply chain consolidation. A distributor selling into the Gulf and Southeast Asia, or a brand owner running the United States alongside the European Union, can place a single order against a single quality system rather than assembling the same product from different suppliers for each territory.

"Regulatory fragmentation is one of the least visible costs in this industry," said a spokesperson for Gansu Constar Technology Group. "A brand owner does not usually discover it until they try to expand into a second market and find that their manufacturer cannot follow them there. Building the portfolio ahead of demand is what allows a partner to open a new territory without changing supplier."

Every export shipment is accompanied by destination-specific documentation, including HS codes, Certificates of Compliance, batch quality reports, and the relevant regulatory filings. Constar manufactures across six production facilities in Gansu and Hunan provinces, with a combined capacity of 15 million lenses per month, and supplies distributors and brand owners in more than 40 countries. Constar's market coverage is detailed on its website.

About Gansu Constar Technology Group Co., Ltd.

Founded in 1984, Gansu Constar Technology Group Co., Ltd. is a China-based contact lens OEM and ODM manufacturer. The company operates six production facilities across Gansu and Hunan provinces with a combined capacity of 15 million lenses per month. It is the only contact lens manufacturer in China to hold FDA 510(k) clearance, CE 0197 marking and ISO 13485 certification simultaneously, and additionally holds national market registrations in Australia, Saudi Arabia, Indonesia, Thailand and Vietnam. Constar supplies clear, coloured, toric and cosmetic contact lenses to distributors and brand owners in more than 40 countries.



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