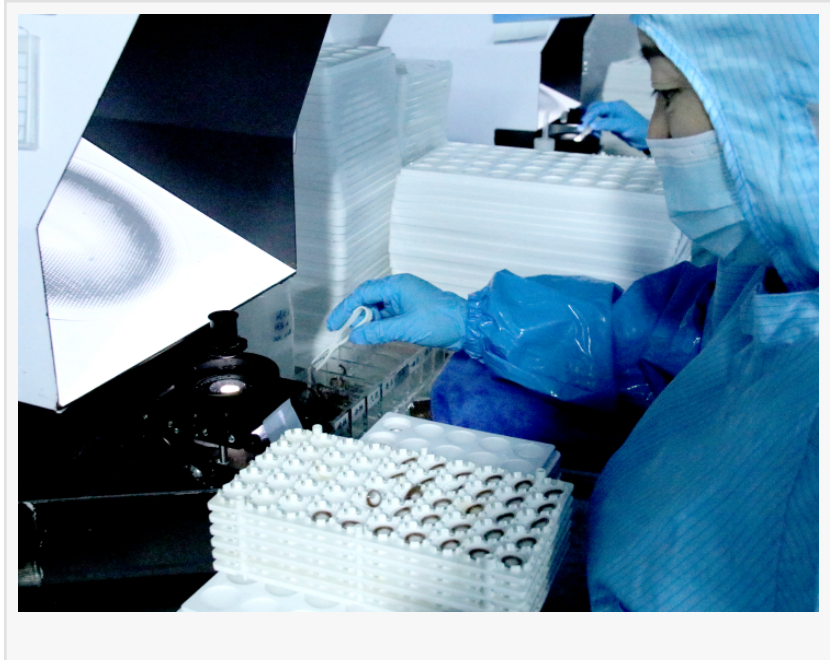


# Constar Becomes Only Contact Lens Manufacturer in China Holding FDA, CE and ISO Triple Certification

BAIYIN, GANSU, CHINA, August 11, 2026 /EINPresswire.com/ -- Chinese manufacturer's unique certification portfolio gives global brand owners unrestricted access to virtually every regulated contact lens market worldwide.

BAIYIN, GANSU, July 24, 2026 — [Gansu Constar Technology Group](#) has confirmed its position as the only [contact lens manufacturer](#) in China holding simultaneous FDA, CE 0197 and ISO 13485 certifications — three credentials that together provide a clear path into virtually every regulated market worldwide.



The certification distinction sets Constar apart in a market where most Chinese manufacturers hold one or two regional certifications but lack the comprehensive portfolio required for multi-market distribution. For brand owners and distributors, the difference is significant: sourcing from a single factory that holds all three core certifications eliminates the need to maintain separate supply chains for different regions.

## What the Three Certifications Cover

Each certification in Constar's portfolio addresses a specific regulatory requirement, and together they cover the vast majority of the global contact lens market.

## FDA Clearance — United States

The U.S. Food and Drug Administration classifies contact lenses as Class III medical devices, requiring establishment registration, device listing and 510(k) premarket notification. Constar's FDA clearance allows its partners to sell contact lenses in the United States — the world's largest single market for optical products — without the compliance barriers that block non-registered

manufacturers.

In 2026, the FDA has intensified enforcement of contact lens registration requirements, with multiple retail seizures of non-FDA-registered colored contact lenses. For brand owners targeting the U.S. market, FDA compliance is no longer optional — it is a legal requirement with real enforcement consequences.

#### CE 0197 — European Union

CE marking under the European Union's Medical Device Regulation 2017/745 is mandatory for selling contact lenses in the European Economic Area. The CE 0197 designation indicates compliance with the specific notified body requirements for optical medical devices, including clinical evaluation, biocompatibility testing and post-market surveillance.

The European Union represents approximately 26 percent of the global colored contact lens market, and CE compliance is increasingly required by distributors across the region. Constar's CE 0197 certification allows partners to access this market without sourcing from European manufacturers.

#### ISO 13485 — Global Quality Management

ISO 13485 is the international standard for quality management systems specific to medical devices. While not a market-specific certification like FDA or CE, ISO 13485 demonstrates a manufacturer's commitment to consistent quality processes, document control, corrective and preventive actions and management review.

ISO 13485 certification is recognized by regulatory authorities worldwide and serves as a baseline requirement for manufacturers seeking additional regional certifications. It provides brand owners with assurance that the manufacturer maintains documented quality systems across design, production and distribution.

#### Why Triple Certification Matters for Brand Owners

The practical value of Constar's triple certification is not just compliance — it is supply chain simplification. Brand owners who source from manufacturers holding only one or two certifications face a fragmented supply chain: one factory for U.S. products, another for European products, a third for Asian markets.

Constar's portfolio eliminates this fragmentation. A single sourcing relationship provides access to:

The United States through FDA clearance

The European Union through CE 0197 marking

Global markets through ISO 13485 quality management certification

Regional markets through additional approvals including AKL for Indonesia, TGA for Australia and SFDA for Saudi Arabia

"A distributor in Dubai, a brand owner in New York and an e-commerce seller in Jakarta all need different certifications from their manufacturer," said Michael Zhang, Director of Business Development at Constar. "Our portfolio means they can source from one factory and sell across all those markets. That is a supply chain advantage that very few manufacturers anywhere in the world can offer."

### The Compliance Landscape Is Tightening

Constar's triple certification becomes more valuable as regulatory requirements intensify globally. The FDA's increased enforcement in 2026, the European Union's stricter post-market surveillance requirements under MDR and the growing number of Southeast Asian countries implementing contact lens registration systems all raise the bar for manufacturers and the brands that source from them.

For brand owners evaluating manufacturing partners, the question is no longer whether a manufacturer holds a single certification — it is whether the manufacturer's certification portfolio covers every market where the brand plans to sell. A CE mark alone does not satisfy FDA requirements. An FDA registration alone does not satisfy CE requirements. Only a manufacturer holding all three core certifications provides the comprehensive coverage that global brands demand.

### Verification and Transparency

Constar provides full certification documentation to prospective partners, including copies of FDA establishment registration, CE 0197 certificate numbers and ISO 13485 audit reports. Certificate numbers can be verified directly with the issuing bodies, and the company maintains an active compliance monitoring process to ensure all certifications remain current.

For brand owners and distributors seeking a manufacturing partner with verified multi-market compliance, Constar's certification portfolio and compliance documentation are available for review upon request. The company also offers complimentary regulatory consultations to help partners understand the specific certification requirements for their target markets.

To request [certification documentation, regulatory consultations or product samples](#), contact Constar's international business team directly.

### About Gansu Constar Technology Group

Gansu Constar Technology Group Co., Ltd. is a China-based contact lens manufacturer specializing in OEM and ODM services for global brands and distributors. Founded more than 40 years ago and headquartered in Baiyin, Gansu Province, the company operates six production facilities with a combined capacity of 15 million lenses per month. Constar holds FDA, CE 0197 and ISO 13485 certifications — the only contact lens manufacturer in China to hold all three simultaneously — and serves partners in more than 50 countries. For more information, visit [www.constarfactory.com](http://www.constarfactory.com).

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