

Constar Factory Announces FDA 510(k) Cleared Contact Lens OEM Solutions for US Importers and Private Label Brands



Baiyin, Gansu Sep 4, 2026 ([Issuewire.com](https://www.issuewire.com)) - FDA-cleared contact lens manufacturer offers private label contact lenses, custom contact lens OEM production, and wholesale contact lens supply with minimum orders from 1,000 pairs

Constar Factory, a leading [contact lens manufacturer](#) and [contact lens OEM supplier](#) with over 40 years of industry experience, today announced its expanded **OEM contact lens solutions** for US-based importers, optical distributors, and private label brand owners seeking **FDA 510(k) cleared contact lens products** for the American market.

With the US **contact lens market** exceeding \$4.5 billion annually and growing at 5% year-over-year, Constar Factory is uniquely positioned to serve **contact lens distributors**, retail optical chains, online contact lens brands, and **private label contact lens** entrepreneurs looking to launch or expand their own-label **soft contact lens** lines. The company's complete **contact lens OEM service** eliminates the burden of navigating complex **FDA regulatory requirements** independently, enabling faster time-to-market for new brands.

Full FDA 510(k) Compliance for US Contact Lens Import

Constar Factory holds valid **FDA 510(k) clearance** for its complete range of **soft contact lenses**, including **daily disposable contact lenses**, **monthly contact lenses**, **colored contact lenses**, **cosmetic contact lenses**, and **toric contact lenses** for astigmatism correction. The company's state-of-the-art **contact lens manufacturing facility** operates under **ISO 13485 quality management systems** and maintains **CE MDR certification**, providing US importers with all documentation required for seamless **US Customs and Border Protection (CBP)** clearance and **FDA inspections**.

"US importers can begin **distributing contact lenses** immediately without waiting for their own **FDA clearance process**," said a Constar Factory spokesperson. "Our existing **510(k) clearance** covers the products we manufacture, which means our partners can focus on building their **contact lens brand** while we handle the **regulatory complexity**. Whether you need **clear contact lenses**, **colored prescription lenses**, or **decorative cosmetic lenses**, every product ships with complete **FDA documentation**."

The company's **FDA compliance** covers **biocompatibility testing** per **ISO 10993**, **sterilization validation**, **packaging integrity testing**, and **clinical evaluation** — all critical requirements for **contact lens registration** and market entry in the United States.

Low MOQ Contact Lens OEM: Minimum Orders from 1,000 Pairs

Unlike traditional **contact lens factories** requiring orders of 10,000 pairs or more, Constar Factory offers **minimum order quantities (MOQ)** starting at just **1,000 pairs per design**. This low barrier to entry enables new **contact lens brand** owners, startup optical companies, and independent **contact lens distributors** to test the US market with manageable inventory investment before committing to large-scale **contact lens production**.

The company provides complete **OEM contact lens services** including:

- **Custom contact lens design** — Multiple base curves, diameters, and water content options
- **Private label contact lens packaging** — Full custom box design with brand artwork
- **FDA-compliant labeling** — Meeting 21 CFR Part 801 requirements for US market
- **Colored contact lens OEM** — Over 200+ color designs in plano and prescription
- **Daily disposable lens OEM** — HEMA and silicone hydrogel materials
- **Brand registration support** — Assistance with FDA establishment registration

Full **contact lens OEM pricing**, product specifications, and **MOQ details** are available at <https://www.constarfactory.com/contact-lens-oem-moq-constar/>

Complete Contact Lens Import Documentation for US Customs

Every shipment from Constar Factory includes the full suite of **contact lens import documents** required for US market entry:

- **FDA 510(k) Clearance Letter** — Proof of device clearance
- **FDA Establishment Registration** — Manufacturer registration confirmation
- **Device Listing Number** — FDA device listing for each lens model
- **Certificate of Analysis (COA)** — Batch-specific quality test results

- **Certificate of Compliance (COC)** — Manufacturing standards compliance
- **Biocompatibility Test Reports** — ISO 10993 cytotoxicity and sensitization
- **ISO 13485 Certificate** — Quality management system certification
- **Sterilization Validation** — EtO sterilization records
- **Packing List & Commercial Invoice** — Standard shipping documentation

US importers receive all files needed for **CBP clearance**, **FDA facility inspections**, and **post-market surveillance** requirements. For a complete step-by-step guide on **how to import contact lenses to the United States**, Constar Factory has published a comprehensive **FDA compliance guide** at <https://www.constarfactory.com/how-to-import-contact-lenses-to-the-united-states/>

US Contact Lens Market Opportunity: \$4.5 Billion and Growing

The **US contact lens market** continues to grow at approximately 5% annually, driven by increasing adoption of **daily disposable contact lenses**, rising demand for **colored cosmetic contact lenses** among younger demographics, and expanding online **contact lens sales** channels. **Private label contact lens brands** capture significant market share by offering competitive pricing, unique designs, and specialized lens types that differentiate from major manufacturers like Johnson & Johnson, CooperVision, and Alcon.

Key **US contact lens market** trends creating opportunities for importers include:

- **Daily disposable lenses** now represent over 40% of the US market
- **Colored contact lenses** growing at 8% annually, driven by social media and fashion trends
- **Online contact lens sales** account for over 30% of total market revenue
- **Silicone hydrogel lenses** gaining share for extended wear comfort
- **Toric and multifocal lenses** growing as aging population increases demand

Constar Factory manufactures over **15 million contact lenses per month** across its production facilities, with capacity to scale for **large-volume US distribution partnerships**. The company's production capabilities include **cast molding**, **spin casting**, and **lathe cutting** for specialty lens designs.

About Constar Factory: 40 Years of Contact Lens Manufacturing Excellence

Constar Factory is a Hong Kong-based **contact lens manufacturer** established in 1986, specializing in **OEM and ODM contact lens production** for global markets. The company holds **FDA 510(k) clearance**, **CE MDR certification**, and **ISO 13485 registration**, making it one of the few **contact lens factories** in Asia with simultaneous access to US, European, and international markets.

Constar Factory supplies **contact lenses** to **distributors**, **optical chains**, **online retailers**, and **private label brand owners** in over 40 countries worldwide, with particular strength in North America, Europe, Southeast Asia, and the Middle East. The company's product range includes **clear contact lenses**, **colored contact lenses**, **daily disposables**, **monthly lenses**, **annual lenses**, **toric lenses**, **multifocal lenses**, and **cosmetic plano lenses**.

For more information about **contact lens OEM partnerships**, **private label opportunities**, or to request product samples, visit <https://www.constarfactory.com/contact>

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