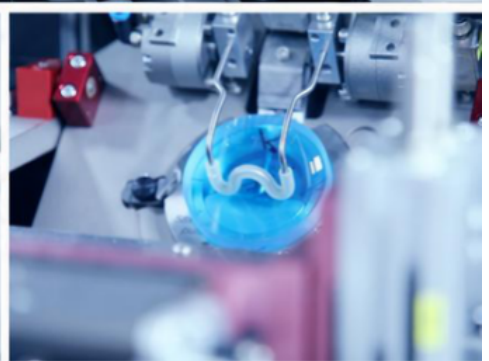


OEM Private Label Optical Lenses: Why CE-Compliant and FDA-Registered Supply Chains Matter



Korean Manufacturing Technology

Strict Quality Control



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Zhenjiang, Jiangsu Aug 2, 2026 ([Issuewire.com](https://www.issuewire.com)) - For global distributors, optical labs, and retail chains, launching a private-label lens brand requires balancing product quality, supply continuity, and strict regulatory compliance. A major risk in cross-border lens procurement is supply chain disruption caused by documentation gaps at customs or non-compliance with regional medical device frameworks. Partnering with an [OEM Private Label Optical Lenses Manufacturer](#) that maintains valid

registrations and complies with international standards—such as CE requirements in Europe and FDA registration in the United States—is essential for smooth market access, risk management, and long-term brand security.

Global Market Access & Regulatory Testing Framework

To support international market entry, private label procurement should be supported by appropriate technical documentation, quality systems, and product compliance information. Below is the operational compliance matrix maintained across our export divisions:

Deconstructing CE Mark Compliance: The European Standard

In the European Economic Area (EEA), ophthalmic lenses are classified as Class I medical devices under the European Medical Device Regulation (EU MDR 2017/745). CE compliance signifies that the manufacturer adheres to fundamental European health, safety, and performance standards.

For private-label brands entering European markets, sourcing from a CE-compliant supplier ensures access to essential technical data. This includes compliance with harmonized standards such as EN ISO 14889, which specifies fundamental requirements for uncut optical lenses. Key parameters—including spherical power, astigmatic tolerance, and optical clarity—must meet established international guidelines. Additionally, raw materials and coatings are evaluated to ensure biocompatibility under ISO 10993 guidelines, reducing the risk of skin irritation during daily wear. Working with a CE-compliant manufacturer helps private-label brands meet local market entry requirements and maintain proper technical documentation.

Navigating FDA Medical Device Registration: The Gateway to the United States Market

In the United States, spectacle lenses are classified as Class I medical devices regulated by the Food and Drug Administration (FDA). Overseas manufacturers supplying the U.S. market must maintain active foreign establishment registrations and device listings before products can clear U.S. Customs.

A key requirement for lenses entering the U.S. market is impact resistance verification, as outlined in 21 CFR 801.410 (commonly known as the Drop Ball Test). In this standard test, a 5/8-inch steel ball weighing approximately 0.56 ounces is dropped from a height of 50 inches onto the horizontal surface of the lens to confirm structural integrity.

CONVOX performs impact resistance verification according to applicable quality requirements to help ensure resin substrates meet mechanical durability expectations. Partnering with an FDA-registered manufacturer helps private labels avoid customs holds and maintain stable, reliable shipments to the U.S. market.

Operational Infrastructure and Quality Assurance

Sustaining consistent manufacturing standards requires modern automated infrastructure. Advanced facilities invest in specialized production machinery to maintain tight tolerances and high batch-to-batch consistency.

CONVOX operates a modern manufacturing facility equipped with dedicated automated production lines. For custom prescription processing, the factory utilizes advanced digital surfacing equipment, including VFT-Orbit series RX systems, allowing precise fabrication of complex geometries and

freeform progressive designs.

After surfacing or casting, lenses move to vacuum coating chambers equipped with 16 advanced NVC coating units. This controlled cleanroom environment applies uniform anti-reflective, hard, and hydrophobic coatings. Every production batch undergoes a 5-procedure quality inspection covering visual clarity, surface cosmetic quality, and power accuracy prior to final packaging.

Long-Term Brand Equity and Commercial Advantages

Sourcing from a verified, compliant OEM manufacturer strengthens a private label's market standing. Eye care professionals, optical retail chains, and institutional buyers increasingly prioritize suppliers who can present clear compliance documentation and steady product quality.

Furthermore, a structured manufacturing baseline improves operational efficiency. By partnering with a factory that maintains a large ready-stock inventory alongside custom manufacturing capabilities, distributors can manage inventory more effectively, shorten lead times, and scale their private-label product lines with confidence.

For more details on custom OEM/ODM optical lens manufacturing capabilities and private-label packaging support, please visit the official corporate platform at [\[https://www.convoy-optical.com/\]](https://www.convoy-optical.com/).

Private Label OEM Workflow

1. Product Selection: Confirm lens materials, designs, coatings, and target market requirements.
2. Sample Approval: Review samples and confirm optical performance, appearance, and packaging details.
3. Branding Preparation: Finalize logo, envelope design, barcode requirements, and labeling specifications.
4. Trial Order: Validate production process and commercial requirements before mass production.
5. Mass Production & Shipment: Complete quality inspection, packaging, and international delivery according to agreed specifications.

FAQ: International Compliance & OEM Operations

Q1: Can CONVOX provide formal Drop Ball Test certification documentation for US Customs clearance?

A1: Yes. Upon request, our quality assurance department can provide available impact resistance test documentation to support customer quality and import documentation requirements.

Q2: How does CONVOX support private labels with custom lens packaging and envelope branding?

A2: We offer complete OEM/ODM customized packaging. Clients can submit their specific brand logo, color layouts, layout parameters, and barcode requirements. We print and pack the finished or semi-finished lenses into your branded envelopes at our factory, delivering retail-ready stock.

Q3: Does CONVOX maintain valid U.S. FDA registration and CE compliance documentation?

A3: CONVOX maintains applicable registration and technical documentation to support customers' compliance requirements. We can provide standard technical datasheets, quality certificates, and

material safety documentation according to project needs.

Q4: Can we incorporate unique private laser markings on our custom progressive lens orders?

A4: Yes. Our automated digital freeform production lines can be programmed to include customized laser markings (such as brand identifiers or addition indicators) on the outer lens surface according to your specific portfolio guidelines.

Corporate Website: [<https://www.convox-optical.com/>]

Contact Email: sales@convox.cn

Secure Your Private Label Infrastructure:

Planning a private brand launch or looking to switch to an internationally compliant manufacturer? Contact our OEM Export Division today to request our regulatory documentation packets, review envelope template dimensions, and obtain a complete factory pricing brief.



Target Market	Regulatory Status / Law	Core Testing & Documentation Requirement	Private Label Quality Insurance Factor
European Economic Area	Medical Device Regulation (EU MDR 2017/745) Class I.	EN-ISO-14889 / ISO-10993 (Optical performance limits, structural <u>biocompatibility</u> , safety data sheets).	Full batch tracking from polymer base monomer blending to local customized packaging.
United States	US FDA Title 21 CFR Part 820 Compliance.	21 CFR 801.410 Drop Ball Test (Mechanical verification using a 0.56-oz steel ball impact resistance test).	Smooth customs clearance verified via valid foreign establishment factory registration.
International Tenders	Quality Management Systems	ISO 9001 Certification / Documented cGMP practices across chemical casting lines.	High batch-to-batch structural integrity, reducing downstream laboratory cutting failure rates.
Custom OEM Output	Tailored Branding Schemes	Private laser marking integration, custom <u>barcode</u> printing, and corporate envelope design.	Better control over brand presentation and supply consistency through structured private label execution.

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