

Contact Lens Import Compliance in 2026: A 10-Country Compliance Map from Constar



Baiyin, Gansu Aug 20, 2026 ([Issuewire.com](https://www.issuewire.com)) - BAIYIN, GANSU, CHINA — Few products travel with more paperwork than contact lenses. Classified as medical devices in almost every regulated market, lenses must clear registration, certification, and import hurdles that **differ from one country to the next** — no two markets file the same documentation or accept the same approvals. A CE mark does not satisfy the US FDA, an FDA 510(k) does not unlock China, and India will run its own assessment even when a product is already approved in Europe and America. For distributors, this article was compiled as a 2026 field guide by [Constar \(Gansu Constar Technology Group\)](#), a China-based contact lens OEM and ODM manufacturer exporting to more than 40 countries, and maps the contact lens import compliance picture across ten major markets — covering regulator, route to market, local representative requirements, and what buyers must verify before shipping a container.

This 10-country map is organized into quick-reference entries so distributors and brand owners can compare requirements at a glance and prioritize the certification work that unlocks their target markets.

Contact Lens Import Compliance at a Glance

- **Local representative is mandatory in most markets** — EU, UK, China, Japan, Australia, Canada, India and South Korea all require a local agent, sponsor, MAH or Responsible Person.
- **One approval never covers another market.** CE, FDA, TGA and CDSCO each run independent assessments.
- **Certification breadth is the real competitive advantage** — fewer than a handful of global factories hold FDA, CE 0197 and ISO 13485 simultaneously.
- **Prescription rules vary by market but lean to mandatory** — most regulated economies require a valid prescription for all lenses, cosmetic lenses included.

1. United States — FDA (Class II / 510(k))

Lenses fall under 21 CFR Part 886 and require establishment registration, device listing and premarket clearance via the **510(k)** pathway — or full **PMA** for higher-risk products. Foreign manufacturers must appoint a **US Agent**, and a valid prescription is required for all lenses under the [FDA Contact Lenses program](#) and the FTC Contact Lens Rule. Clinical data is typically needed in only about 10% of 510(k) submissions, which keeps the US pathway comparatively fast for conventional lenses.

2. European Union — CE Marking under MDR 2017/745

Since May 2021, lenses need a **CE mark** assessed by an independent notified body under Medical Device Regulation (EU) 2017/745 — see the official regulation text at [EUR-Lex](#). Lenses are typically **Class IIa/IIb**; the optical-device notified body designation **CE 0197** is held by only a small number of organizations worldwide. Non-EU manufacturers must appoint an **EU Authorized Representative**, maintain technical documentation for 10 years, and comply with UDI requirements (mandatory since 2021) and post-market surveillance under Article 61.

3. United Kingdom — MHRA / UKCA

Post-Brexit, lenses entering Great Britain require **UKCA marking** (with CE transition still in effect for many products) and **MHRA registration** before market placement. A **UK Responsible Person** is mandatory for manufacturers based outside the UK, and prescriptions are enforced by optometrists under existing practice frameworks.

4. China — NMPA (Class III)

China treats contact lenses as **Class III devices**, its highest-risk category, regardless of the class assigned in the country of origin. Requirements include NMPA registration, **in-country type testing** (only biocompatibility per ISO 10993 / GB 16886 is accepted from abroad), a mandatory **local agent**, and proof of home-market approval. Full registration is typically a multi-year, six-figure exercise.

5. Japan — PMDA / MHLW

Under Japan's **PMD Act**, lenses are classified at Class II or III and require marketing authorization through the Pharmaceuticals and Medical Devices Agency (PMDA). Foreign manufacturers must appoint a Japan-based **Marketing Authorization Holder (MAH)**, hold Japanese QMS (J-QMS) audits, and work through a registered certification body for Class II devices.

6. Australia — TGA (ARTG)

Lenses are **Class IIa/IIb** devices requiring **ARTG inclusion** before sale, with a mandatory **Australian**

local sponsor that holds legal responsibility. Advertising of contact lenses to the public is restricted, so marketing must run through the practitioner channel.

7. Canada — Health Canada

Health Canada regulates lenses as **Class II/III** devices requiring a **Medical Device License** (Class III), plus an **Establishment License** for importers and distributors. An **ISO 13485** quality system is effectively required to demonstrate compliance.

8. Saudi Arabia — SFDA

The Saudi Food and Drug Authority (**SFDA**) requires product registration before lenses can be imported across GCC markets, with **Arabic-language labeling and documentation** mandatory for customs clearance. Lenses are increasingly treated under full medical-device registration rules as the region's beauty optics demand grows.

9. India — CDSCO (MDR 2017)

India's regulatory net closed around all medical devices in 2026. Importing agencies must hold a **CDSCO import license (Forms MD-14 / MD-15)** via the SUGAM portal, and **contact lenses now require mandatory BIS certification under IS 15923**. Foreign manufacturers must appoint an **Indian Authorized Agent (IAA)**, supply a Free Sale Certificate from the country of origin (not older than 2 years), and demonstrate ISO 13485. Registration typically takes 6–12 months.

10. South Korea — MFDS

Lenses are **Class II/III** under the Ministry of Food and Drug Safety (**MFDS**), requiring preliminary **KFDA/MFDS approval** before import. A **licensed local importer** is mandatory, Korean-language labeling is required, and documentation must be submitted in Korean.

Southeast Asia: A Patchwork Within a Region

Southeast Asia is the least uniform region. Indonesia requires **AKL approval**; Vietnam uses a tiered system assigning lenses to **Class B** with a different dossier than Class A; Thailand's TFDA requires product registration plus a local representative; Malaysia enforces its own **Medical Device Authority** standards. Suppliers with region-specific certifications — like the [multi-market compliance portfolio Constar maintains across 40+ countries](#), spanning FDA, CE 0197, TGA, SFDA, AKL and Vietnam Class B — remove the need to source from different factories for different geographies.

What Distributors Should Verify Before Placing an Order

- **Market-specific certifications, not one general credential.** A CE mark alone does not satisfy an FDA, NMPA or CDSCO, and vice versa.
- **Batch-level documentation.** Request Certificates of Analysis, biocompatibility test reports and material safety data sheets with every shipment.
- **A proven customs track record.** Established manufacturers will have documented processes for import clearance in your target region — the difference between a clean landing and a seized container.

Frequently Asked Questions Is a CE mark enough to import contact lenses into any country?

No. CE marking only covers the European Economic Area. The US FDA, China's NMPA, Japan's PMDA, India's CDSCO and every other major regulator run independent assessments, and most also require a local representative for the importing manufacturer.

Do all countries require contact lens import registration?

In any regulated market, yes. Contact lenses are classified as medical devices, so registration or authorization is required before import — plus, in most markets, a doctor-issued prescription to sell them. Markets without such controls are where counterfeit and unapproved lenses circulate.

Why do contact lens compliance requirements change so often?

Because medical device rules are continuously tightening — from the EU MDR 2017/745 to China's NMPA Class III regime to India's 2026 mandatory BIS certification (IS 15923). Buyers should re-verify compliance requirements annually before renewing supplier contracts.

About Constar

Gansu Constar Technology Group Co., Ltd. is a [China-based contact lens OEM and ODM manufacturer](#) serving brands and distributors in more than 40 countries. Founded more than 40 years ago and headquartered in Baiyin, Gansu Province, the company operates six production facilities with a combined capacity of over **15 million lenses per month**, and holds US FDA (510(k), Class II), EU CE 0197 (MDR), ISO 13485, TGA, SFDA, AKL and Class B (Vietnam) certifications.

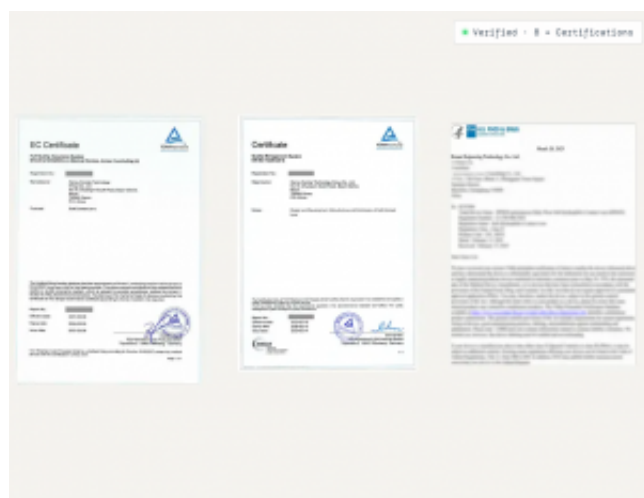
Sources:

FDA — Contact Lenses (Medical Devices Program)

EUR-Lex — Medical Device Regulation (EU) 2017/745

CDSCO — Medical Device Rules 2017 (Forms MD-14 / MD-15)

Constar — Markets We Serve



Media Contact

Gansu Constar Technology Group CO.,LTD

*****@constarfactory.com

<https://www.constarfactory.com/>

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