10-B Udham Singh Nagar, Ludhiana (Punjab) 141001
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Mandatory requirements	Recommended requirements
(a) FDA registration and listing Exporters must register their establishment with FDA as medical device establishment. Exporters are also required to list their devices with FDA post registration of establishment **(b) Certification** Exporters of spectacles/ sunglasses must ensure that the lenses are tested and certified for impact resistance **(c) Product Labelling** Product labelling should be as per the FDA guidelines which provides directions on various declarations on the labels, Unique Device Identification procedure, directions to use etc	**Quality system requirements** Exporters must meet the Quality system requirements as per FDA to ensure the quality standards of their product

FAQs:

1. **When are the compliance requirements needed?**
   All requirements are to be completed before exporting the products to USA

2. **How often are the requirements needed?**
   (a) Medical device establishment registration shall be required once and shall be renewed at annual intervals
   (b) Listing of the device with FDA shall be required once for every product
   (c) Adhering to Quality system is the continuous requirement
   (d) Impact resistant testing and certification shall be required once for each lot of production
   (e) Product labeling is required once for every product, unless there is a change in the regulations

3. **Links for reference:**
   (a) FDA registration and listing: https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/sunglasses-spectacle-frames-spectacle-lens-and-magnifying-spectacles

   (b) Impact resistant testing:
   https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=801.410

   (c) Product Labeling guide:
   https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=801

   (d) Quality System Requirements:
   https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820

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Additional requirements:

If the products have chemical components, a **MSDS** (Material Safety Data Sheet) and a **COA** (Certificate of Analysis) are required with the shipment. These documents are prepared by the manufacturer and helps to understand the potential health and physical hazards of the chemical components, details of lab testing reports and product specifications like components, characteristics, etc. COA is issued for every batch of production.

Link for reference on MSDS: https://www.osha.gov/sites/default/files/publications/OSHA3514.pdf