US and EU PPE Eyewear Testing Regulations

May 7, 2020
Meet Today’s Speaker

Davio Tsang, QIMA Eyewear Technical Consultant

➤ Davio has 10 years’ experience in the eyewear manufacturing industry. She also has almost 10 years’ experience in the testing service industry.

➤ Davio works closely with domestic manufacturers, buyers in Europe, the US and other regions, as well as optical chain stores, distributors and more.

➤ Davio has collaborated with HKOMA (Hong Kong Optical Manufacturers Association) and Hong Kong Productivity (HKPC) to hold seminars on eyewear testing requirements and regulations and has attended technical conferences hosted by The Vision Council in the US.
About QIMA

Our Team of 2,500+ Qualified Inspectors, Auditors and Lab Engineers Perform Services in 85 Countries

In 2020, we will deliver more than 400,000 inspection, audit, testing and certification reports for brands, retailers and importers globally.
Dedicated Lab Testing Capabilities For the Eyeglass Industry

We Evaluate Product Safety and Compliance Against International Standards

- 6 fully accredited in-house labs in the US, France, Hong Kong and China providing testing services for toys, non-durable goods, glasses, gifts and accessories
- The first accredited HOKLAS laboratory in Hong Kong for eyeglasses
- Test reports recognized by BSI and SAI for CE certification (EU) and Benchmark Product Certification (Australia) on Personal Eye Protection Devices
- Capacities for physical and mechanical testing, nickel release, flammability and corrosion testing, lens and optical testing, impact resistance, optical and UV radiation aging
- Ability to provide custom-made test programs to meet specific client requirements
# Dedicated Lab Testing Capabilities For the Eyeglass Industry

We Evaluate Product Safety and Compliance Against International Standards

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<tr>
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<td></td>
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<td></td>
<td>• AS/NZS 1338.1, AS/NZS 1338.2, AS/NZS 1338.3</td>
</tr>
</tbody>
</table>
Memberships & Associations

QIMA is a Member of Key Eyewear Manufacturer's Associations

Our memberships ensure we bring the latest eyewear industry information to our clients.

Memberships:
- Hong Kong Manufacturers Association (HKOMA)
- Federation of Hong Kong Industries (FHKI)
- Technical committee member of The Vision Council in US
- Member of China Optical Association (COOA)
EU Regulations for Eyewear Products

Medical Device Regulations and Personal Protective Equipment Regulations
Medical Devices

Regulation (EU) 2017/745 (MDD 93/42/EEC) Ophthalmic Optics

- Spectacle frame requirements – EN ISO 12870-2016
- Spectacle lenses on uncut single vision, bifocal or progressive lenses with/without anti-reflective coating and resistance to abrasion coating – EN ISO 14889 and EN ISO 8980 part 1 to 5 (wherever applicable)
- Mounted prescription lenses – EN ISO 21980
- Ready-to-wear near vision spectacles – EN14139 (reading glasses ISO 16034)
- Nickel release refer – EN16128-2015
Personal Protective Equipment


- Sunglasses with sun glare filters
  – ISO 12312-1
- Sun glare filter for direct observation of the sun – ISO 12312-2
- Swim goggles – BS 5883
- Ski goggles – EN 174
- Goggles for motorcycle use – EN 1938
- Goggles for snowmobile use – EN 13178
- Safety-spectacles with prescription lenses – EN166 Rx
- Safety eye protectors and face shield with PLANO lenses refer to EN166, filters refer to EN169, En170, EN171 and EN172
EU Directive vs. EU Regulation

What’s the Difference?

EU Directive

➤ A legislative act that sets out a goal that all EU countries must achieve. It is up to the individual countries to devise their own laws on how to reach this goal

➤ For example, the EU consumer rights directive eliminates hidden charges and costs on the internet and extends the period under which consumers can withdraw from a sales contract

EU Regulation

➤ A binding legislative act that must be applied in its entirety across the EU

➤ For example, when the EU wanted to make sure that there are common safeguards on goods imported from outside the EU, the Council adopted a regulation
CE Marking

When Does it Mean?

- The letters CE stand for "Conformité Européenne" which means “European Conformity”.
- The CE marking symbolizes the conformity of the product with the applicable community requirements imposed on the manufacturer.
- The CE marking affixed to products is a declaration by the person responsible that the product conforms to all applicable community provisions and that the appropriate conformity assessment procedures have been completed.
Personal Protective Equipment

Regulation (EU) 2016/425

What is Personal Protective Equipment (PPE)?

▷ Personal protective equipment (PPE) are products that the user can wear or hold, to be protected against risks either at work, at home or whilst engaging in leisure activities.

EU Legislation and PPE

▷ Regulation (EU) 2016/425 of 9 March 2016 covers the design, manufacture and marketing of PPE.

▷ It defines legal obligations to ensure that PPE on the EU internal market provides the highest level of protection against risks.

▷ The CE marking affixed to PPE provides evidence of compliance of the product with the applicable EU legislation.
Examples of Personal Protective Equipment

PPE Eyewear Comes in Many Forms

A. Spectacle, No sideshield
B. Spectacle, Half Sideshield
C. Spectacle, Full Sideshield
D. Spectacle, Detachable Sideshield
E. Spectacle, Non-Removable Lens
F. Spectacle, Lift Front
G. Cover Goggle, No Ventilation
H. Cover Goggle, Indirect Ventilation
I. Cover Goggle, Direct Ventilation
J. Cup Goggle, Direct Ventilation
K. Cup Goggle, Indirect Ventilation
L. Spectacle, Headband Temple
M. Cover Welding Goggle, Indirect Ventilation
N. Faceshield
O. Welding Helmet, hand Hold
P. Welding Helmet, Stationary Window
Q. Welding Helmet, Lift Front
R. Respirator
S. Respirator
T. Respirator
U. Respirator
## PPE Eye Protectors

### Categories and Types

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<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
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<td>Manufacturers self declaration</td>
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</tr>
<tr>
<td>Simple PPE</td>
<td></td>
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<td>Manufacturers self declaration</td>
</tr>
<tr>
<td>Category II</td>
<td>Initial product approval</td>
<td>Article 10 EC Type Examination</td>
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</tr>
<tr>
<td>Intermediate PPE and</td>
<td></td>
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</tr>
<tr>
<td>Category III</td>
<td>On-going surveillance through testing</td>
<td></td>
<td>Module C (Annex VI)</td>
</tr>
<tr>
<td>Complex PPE only</td>
<td></td>
<td>Article 11A</td>
<td>Module C2 (Annex VII)</td>
</tr>
<tr>
<td>Category III</td>
<td>On-going surveillance through factory auditing</td>
<td>Article 11B</td>
<td>Module D (Annex VIII)</td>
</tr>
<tr>
<td>Complex PPE only</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**or**

- Module C2 (Annex VII)
- Module D (Annex VIII)
PPE Eye Protectors

Categories and Types

Category I: Simple PPE

- Designed to protect users against minimal risks such as:
  - Superficial mechanical injury
  - Contact with water or cleaning materials of weak action
  - Contact with hot surfaces not exceeding 50°C
  - Damage to the eyes due to sunlight exposure (other than during observation of the sun)
  - Atmospheric conditions that are not of an extreme nature

- Examples:
  - Sunglasses
  - Swimming goggles

Category II: Intermediate PPE

- Category II includes risks other than those listed in Categories I and III

- Examples:
  - Safety spectacles and goggles
  - Industrial helmets and bump caps
  - Hi-visibility clothing
PPE Eye Protectors

Categories and Types

Category III: Complex PPE

- Includes risks that may cause very serious consequences such as death or irreversible damage to health such as:
  - Substances and mixtures which are hazardous to health
  - Atmospheres with oxygen deficiency
  - Harmful biological agents
  - Ionising radiation
  - High-temperature environments, the effects of which are comparable to an air temperature of at least 100°C
  - Low-temperature environments, the effects of which are comparable to an air temperature of -50°C
  - Falling from a height, electric shock and live working
  - Drowning
  - Cuts by hand-held chainsaws
  - High-pressure jets
  - Bullet wounds or knife stabs
  - Harmful noise
## European Standards Related to PPE Regulation

<table>
<thead>
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<th>Test Standard</th>
<th>Test Methods</th>
<th>Special Claimed Functions</th>
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<tbody>
<tr>
<td>Safety goggles</td>
<td>EN166:2001</td>
<td>EN167/EN168 EN169 EN170 EN171 EN172</td>
<td>• Splash-proof • Anti-fogging • Falling sand • Low/medium impact • Welding/UV/IR/Sun</td>
<td>Certificate to prove materials do not cause skin irritation</td>
</tr>
<tr>
<td>Face Shield</td>
<td>EN166:2001</td>
<td>EN167/EN168 EN169 EN170 EN171 EN172</td>
<td>• Splash-proof • Anti-fogging • Falling sand • Low/medium/high impact • Welding/UV/IR/Sun</td>
<td>Certificate to prove materials do not cause skin irritation</td>
</tr>
<tr>
<td>Ski goggles</td>
<td>EN174</td>
<td>EN174</td>
<td>• Anti-fogging • Falling sand</td>
<td></td>
</tr>
<tr>
<td>Motorcycle</td>
<td>EN1938</td>
<td>EN1938</td>
<td>• Anti-fogging • Falling sand</td>
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<tr>
<td>Snowmobile</td>
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<td>Swimming goggles</td>
<td>BS 5883</td>
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</tbody>
</table>
PPE Category I

Requirements to Import to EU Countries

Before launching a product to market, the manufacturer or the European representative (or the distributor) should provide:

1. **Technical file** consisting of:
   - Product drawing and material list
   - Test report to prove that the relevant tests and have been conducted and fulfilled, and to verify the product complies with essential requirements

2. **Quality plan** to monitor the quality of the products

3. **Declaration letter** declaring that the device complies with the provision of Personal Protective Equipment Regulation (EU) 2016/425

4. **CE Mark** affixed on the device if quality of products are meeting the requirements set by EU markets

**Declaration of Conformity Example**
PPE Category II and/or Category III

Procedures to Apply for Certification

- **Identify a Notified Body** that has a scope of accreditation detailing its competence in terms of directives and regulations on the product types you need.

- **Provide documentation** in compliance with the requirements of the European Regulation No. 2016/425.

- The Notified Body will **review the test reports and technical documentation**. Repeat some tests and check the samples if necessary.

- After fulfilling all requirements of the Regulation 2016/425 and harmonized standards, the Notified Body will **issue the EU Type Certification** valid for Europe.
Testing Items of Safety Goggles and Face Shields

**EN166:2001**

**Mandatory items:**
- Optical requirements
  - Optical quality
  - Luminous transmittance
  - Haze / Diffusion of light
  - Refractive powers
  - UV stability
- Physical requirements
  - General Construction
  - Increased robustness (marking “S”)
  - Ignition
  - Corrosion on metal parts
  - Field of vision
  - Lens surface quality

**Other optional items:**
- Resistance to droplet and splash
- Resistance to fogging
- Resistance to surface damage
- Lateral protection & protection against high speed particles
- Protection against molten metals and hot solids
- Protection against large dust particles
- Protection against short circuit electric arc
- Protection against optical radiation
Markings of PPE Goggles and Face Shields

Printing Requirements on Lens

- Identification of the manufacturer
- Optical class (either 1 or 2)
- Symbol of impact level \(\Rightarrow\) “S”

So there must be: Company code 1 or 2 S \(\Rightarrow\) At least 3 groups of printing
Markings of PPE goggles / Face shield

Printing Requirements on Frame

› Identification of the manufacturer
› The number of the standard: EN166
› Symbol of liquids: Prevention of water “3” (if there is a test, this project must have)
› Symbol of impact level ==> “S”

So there must be: Company code EN166 3 S ==> At least 4 groups + CE logo
Notified Bodies

What is Their Role?

- Notified Bodies are Europe-based organisations that have been appointed by Member State Governments and notified to the European Commission on the basis of their ability to carry out the examinations and tests required for CE marking of products for Europe.
- They must be independent and impartial and have a high level of professional indemnity insurance.
- Each Notified Body will have a scope of accreditation detailing its competence in terms of directives, regulations and products.
- There are currently around 120 PPE Notified Bodies throughout Europe and these are all subject to routine surveillance at regular intervals. It is possible to identify which Notified Body has certified the product because its name, address and unique number has to be displayed on the accompanying user information.
Certification Examples

3 Criteria to Identify a Valid Certificate

1. **Certificate Type**
   EU Type Examination Certificate

2. **Notified Body Number**
   Example: 0497

3. **Assessment Scope**
   Example: PPE eye protection Annex V
Steps to search a Notified Body from NANDO Database

If you have doubts about the Notified Body, you can check the NANDO database where you will find the competences of the Notified Bodies.

Note that not all PPE notified bodies are competent for all types of PPE.

- Regulation (EU) 2016/425 Personal protective equipment
Steps to search a Notified Body from NANDO Database

1. Go to the NANDO Database website.
2. Click on the "Notified bodies" section.
3. Choose the "Country" or "Body" to narrow down the search.
4. Select the "Legislation" for the search criteria.
5. Choose the "Procedure / Article or annex" and "Products" as needed.
6. Click on the "Search" button to find the Notified Body.
7. Review the search results and select the appropriate body.

This process allows you to search for a Notified Body based on specific criteria, making it easier to find the necessary information.
Steps to search a Notified Body from NANDO Database

Notification of a Body in the framework of a technical harmonization directive

From: Ministero della Salute
Economia - Direzione Generale per il Mercato, la Concorrenza, il Consumo, la Vigilanza e la Normativa Tecnica
Via San Giuseppe, 53
00197 ROMA
Italy

To: European Commission
GROWTH Directorate-General
200 Rue de la Loi,
B-1049 Brussels.
Other Member States

Reference: Legislation: Regulation (EU) 2016/425 Personal protective equipment

Body name, address, telephone, fax, email, website:

Body: CSI SPA
Cascina Traversagna, 21
20030 Sanago (MI)
Italy
Phone: +39 02 3839201
Fax: +39 02 3502940
Email: prodotti@csi-spa.com
Website: www.csi-spa.com

Body number: 0497

The body is formally accredited against:
Accreditation standard used EN ISO/IEC 17025 - Product certification. But also the relevant requirements of UNI CEI EN ISO/IEC 17025 have been assessed.

Name of National Accreditation Body (NAB): ACCREDIA
The accreditation covers the product categories and conformity assessment procedures concerned by this notification: Yes

Tasks performed by the Body:

<table>
<thead>
<tr>
<th>Product Family, Product/Intended use/Product Range</th>
<th>Procedure/Modules</th>
<th>Annexes or Articles of the Directives</th>
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<td>Annex V</td>
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<tr>
<td>Equipment providing face protection</td>
<td></td>
<td></td>
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<tr>
<td>Equipment providing hand and arm protection</td>
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<tr>
<td>Protective Equipment against substances and mixtures which are hazardous to health</td>
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</tr>
<tr>
<td>Specialized areas of competence: Protective clothing for automotive users</td>
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<td></td>
</tr>
</tbody>
</table>

Legislations:
- Regulation (EU) No 305/2011 - Construction products
- 2006/42/EC Safety of toys
- 2012/35/EU Transportable pressure equipment
- 2014/23/EU Marine equipment
- Regulation (EU) 2016/425 Personal protective equipment
European Safety Federation – COVID-19

Recommended Reading

The following article published by the European Safety Federation (ESF) is useful resources. From this article, you can find out the following information:

- What to do when importing PPE (e.g. FFP2 masks) to the EU?
- Conformity assessment procedure for PPE
- A list of examples of Fake Certificates

Visit:
Commission Recommendation (EU) 2020/403

**EU Googles and Masks**

- According to the log issued by the European Commission, export of EU goggles and masks (including anti-virus function) to the EU requires compliance with PPE Regulation (EU) 2016/425 and puts forward **recommendations for compliance evaluation and market monitoring procedures** in Commission Recommendation (EU) 2020/403.

- The market supervision agency may allow it to sell within the specified time and the product must continue to complete its conformity evaluation process.

- The competent authorities of the member states can also evaluate and organize the purchase of PPE products without the CE mark during the pandemic. The products can only be provided to the medical workers for use and cannot be sold in the market.

- Recommendations need to be decided by different member states.
Importing PPE Eye and Face Protectors to Italy

Special Arrangement (from end of March 2020)

- Per the conversation with the Italian Notified Body, the Italian government has a special arrangement on the import of PPE eyewear in this critical period of COVID-19.

- If the PPE goggles and face-shields are only to be distributed in Italy (i.e. not for other European countries), they can allowed to launch and distribute with only accredited test reports and other supporting documents to submit to the Italian government.

- It is not necessary to have a Notified Body issue a certificate to launch the products. The self-declaration shall be done by manufacturers or importers only.

DIRETTORE GENERALE

Alien Strutture centrali e territoriali

Oggetto: Emergenza COVID – 19
Attuazione art.15 decreto-legge 17 marzo 2020, n.18
Validazione straordinaria dei dispositivi di protezione individuale

L’art.15 del decreto-legge n.18 del 2020 detta disposizioni straordinarie per la gestione dell’emergenza COVID-19 ed attribuisce all’Inail la funzione di validazione straordinaria ed in deroga dei dispositivi di protezione individuale (dpi).

Fermi restando i poteri del Commissario straordinario ai sensi dell’art. 122 del richiamato decreto-legge, si tratta per l’Inail, che collabora alle misure di mitigazione del rischio COVID-19 in qualità di soggetto attuatore degli interventi di protezione civile, di una competenza nuova attribuita in via straordinaria, per il tempo strettamente necessario, fino al termine dello stato di emergenza, in deroga alle procedure ordinarie.

La deroga ovviamente riguarda la procedura e la relativa tempistica e non gli standard di qualità dei prodotti che si andranno a produrre, importare e commercializzare, che dovranno assicurare la rispondenza alle norme vigenti e potranno così concorrere, unitamente all’adozione delle altre misure generali, al contenimento ed alla gestione dell’emergenza epidemiologica in corso. Terminato il periodo di emergenza, sarà ripreso il percorso ordinario e i dpi, validati in attuazione della disposizione indicata in oggetto, dovranno, per continuare a essere prodotti, importati o commercializzati, ottenere la marcatura CE seguendo la procedura standard.

In considerazione della specifica finalità della norma, i dpi interessati dalla disposizione sono unicamente quelli funzionali a mitigare i rischi connessi all’emergenza sanitaria in corso.

La richiesta deve essere presentata utilizzando il facsimile di autocertificazione predisposto (che per completezza si allega), avendo cura di inserire tutta la documentazione necessaria per la valutazione tecnica, e deve essere inviata esclusivamente alla casella di posta elettronica certificata qipart15@postacert.inail.it.
Medical Devices

Regulation (EU) 2017/745

Medical Devices

What is a Medical Device?

› Any instrument, apparatus, appliance, software or material intended to be used for medical purposes
  › Diagnosis, prevention, monitoring, treatment or alleviation of disease
  › Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, investigation
  › Replacement or modification of the anatomy of or a physiological process
  › Control of conception

› Does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means
Classification of Devices

- Devices shall be divided into Classes I, IIA, IIB and III, taking into account the intended purpose of the devices and their inherent risks.
- Classification shall be carried out in accordance with MDR (EU) 2017/745 Annex VIII.
- Spectacle frames are classified under Medical Device Class I.
## European Standards Related to MD Regulation

<table>
<thead>
<tr>
<th>MD Category</th>
<th>Test Standard</th>
<th>Test Methods</th>
<th>Special Claimed Functions</th>
<th>Chemical Tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spectacle lenses (uncut)</td>
<td>ISO 14889</td>
<td>ISO 14889 ISO 8980.1/2/3 ISO 8980.4/5</td>
<td>*Anti-reflective coating *Resistance to abrasion</td>
<td>-</td>
</tr>
<tr>
<td>Spectacle lenses (cut or mounted)</td>
<td>ISO 21987</td>
<td>ISO 21987 ISO 14889 ISO 8980.1/2/3 ISO 8980.4/5</td>
<td>*Anti-reflective coating *Resistance to abrasion</td>
<td>-</td>
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Medical Devices

Requirements to Import to EU Countries

Before launching the product to market, the manufacturer or the European representative (or the distributor) should provide:

1. **Technical file** consisting of:
   - Product drawing and material list
   - Test report to prove that the relevant tests and have been conducted and fulfilled, and to verify the product complies with essential requirements

2. **Quality plan** to monitor the quality of the products

3. **Declaration letter** declaring the device complies with the provision of Medical Device regulation 2017/745

4. **CE Mark** affixed on the device if quality of products are meeting the requirements set by EU markets


Declaration of Conformity Example
US Regulations for Eyewear Products
Medical Devices

Classification

- Currently medical devices fall into one of three medical device classifications: Class I, Class II, and Class III
  - Class I includes devices with the lowest risk and Class III includes those with the greatest risk
- In some circumstances, devices are unclassified. For more information review the Medical Device Classification Product Codes Guidance for Industry and FDA Staff

Device class and regulatory controls:

- Class I General Controls
  - With Exceptions
  - Without Exceptions
- Class I General Controls and Special Controls
  - With Exceptions
  - Without Exceptions
- Class III General Controls and Premarket Approval

Sunglasses, Spectacle Frames, Spectacle Lenses and Magnifying Spectacles

FDA Regulations

➤ Sunglasses, spectacle frames, spectacle lenses and magnifying spectacles are medical devices exempt from the Premarket Notification 510(k) submission to the Food and Drug Administration (FDA)

➤ Although these devices are 510(k) exempt, several other FDA regulations apply:

  ➤ US manufacturers and initial US distributors (importer) must register their establishment with FDA
  ➤ Foreign manufacturers must register their establishment with FDA and name a United States Agent
  ➤ Manufacturers must list their devices with the FDA
    ➢ Manufacturers must meet Quality System (QS) requirements set forth in 21 CFR 820
    ➢ The lens for spectacles and/or sunglasses must be certified as impact resistant under 21 CFR Part 801.410

➤ Failure to comply with these requirements may result in detention of the device at the US port of entry
## US Standards Related to MD Regulation

<table>
<thead>
<tr>
<th>MD Category</th>
<th>Test Standard</th>
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<tr>
<td>Spectacle frame</td>
<td>ANSI Z80.5</td>
<td>ANSI Z80.5</td>
<td>*optical radiation on frame</td>
<td>Nickel Release EN16128:2015 + CPSIA</td>
</tr>
<tr>
<td>Sunglasses</td>
<td>ANSI Z80.3</td>
<td>ANSI Z80.3</td>
<td>*polarized *photochromic *anti-reflective lens *resistance to abrasion</td>
<td>Nickel Release EN16128:2015 + CPSIA</td>
</tr>
<tr>
<td>Spectacle lenses</td>
<td>ANSI Z80.1</td>
<td>ANSI Z80.1</td>
<td>*Anti-reflective coating *Resistance to abrasion</td>
<td>-</td>
</tr>
<tr>
<td>(uncut)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ready-to-wear readers</td>
<td>ANSI Z80.31</td>
<td>ANSI Z80.31</td>
<td>*Anti-reflective coating *Resistance to abrasion</td>
<td>Nickel Release EN16128:2015 + CPSIA</td>
</tr>
<tr>
<td>老花眼镜</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Swimming goggles</td>
<td>ANSI Z86.11</td>
<td>ANSI Z86.11</td>
<td>-</td>
<td>CPSIA</td>
</tr>
</tbody>
</table>
Medical Device Registration and Listing

Registration

- Businesses that are involved in the production and distribution of medical devices intended for use in the US are required to register annually with the FDA – known as Establishment Registration (Title 21 CFR Part 807).

- Congress has authorized FDA to collect an annual registration fee for device establishments. A detailed list of the device types that are required to register and pay the fee can be found on the FDA website. The fee is not eligible for a reduced small business fee.

- All registration and listing information must be submitted electronically unless a waiver has been granted.

- Registration and listing provides FDA with the location of medical device establishments and the devices manufactured. Knowing where devices are made increases the nation’s ability to prepare for and respond to public health emergencies.

- The schedule of annual registration user fees for fiscal years 2018 through 2019 follows:

<table>
<thead>
<tr>
<th>Year</th>
<th>FY 2018</th>
<th>FY 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fee</td>
<td>$4,624</td>
<td>$4,884</td>
</tr>
</tbody>
</table>
Device Registration and Listing

Device Listing

- Manufacturers of magnifying spectacles, spectacle frames, prescription spectacle lenses and sunglasses must list each of the devices manufactured by the firm.
- **Medical Device Listing** provides instructions on how to list your device.
- The following regulation numbers and product codes are provided for your convenience.

<table>
<thead>
<tr>
<th>Classification Name</th>
<th>Classification Product Code</th>
<th>Title 21 CFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnifying spectacles</td>
<td>HOI</td>
<td>886.5840</td>
</tr>
<tr>
<td>Spectacle frames</td>
<td>HQZ</td>
<td>886.5842</td>
</tr>
<tr>
<td>Prescription Spectacle lens</td>
<td>HQG</td>
<td>886.5844</td>
</tr>
<tr>
<td>Sunglasses</td>
<td>HQY</td>
<td>886.5850</td>
</tr>
</tbody>
</table>
Device Registration and Listing

Device Listing

- The registration of a medical device establishment is a two-step process:
  - First you must pay the annual registration user fee
  - Once you have paid the fee, you can then complete the registration process

- Your registration is not considered complete until you have:
  - Paid your annual registration user fee
  - Submitted your registration and listing information electronically, and
  - Received e-mail notification from the FDA that all requirements have been met
United States Agent

FDA Requirements

- All foreign establishments must notify FDA of the name, address and phone number of their United States agent. The United States agent must either reside in the US or maintain a place of business in the US.

Responsibilities of a US Agent

The responsibilities of a US agent are limited and include:

- Assisting FDA in communications with the foreign establishment.
- Responding to questions concerning the foreign establishment’s devices that are imported or offered for import into the United States.
- Assisting FDA in scheduling inspections of the foreign establishment.
- If FDA is unable to contact the foreign establishment directly or expeditiously, FDA may provide information or documents to the US agent, and such an action shall be considered to be equivalent to providing the same information or documents to the foreign establishment.
Apart from the registration process, the lens for spectacles and/or sunglasses must be certified as impact resistant under 21 CFR Part 801.410
Impact Resistant Lens Requirements

Acceptable sampling methods

- ANSI/ASQC Z1.4/1993, sampling procedures and tables for inspection by attributes
- ISO 2859-1/1999, sampling procedures for inspection by attributes – Part 1: Sampling schemes indexed by Acceptance Quality Limit (AQL) for lot-by-lot inspection
- MIL-STD 105, Military Standard “Sampling Procedures and Tables for Inspection by Attributes” at an Acceptable Quality Level (AQL) of 6.5, general inspection level II

See Impact-Resistant Lenses: Questions and Answers for additional guidance
Guidance for the Industry

Recommended Reading

"Guidance Document for Non-prescription Sunglasses" assists manufacturers, distributors, importers and other interested persons in understanding the regulatory requirements that are applicable to sunglasses.
Country of Origin Marking Requirements

19 U.S.C Section 1304

- Goods that are imported into the US are required to have a Country of Origin marking, such as the country of manufacture, production, or growth of any article of foreign origin entering the United States.

- There are exceptions to this requirement. For instance, for goods that are incapable of being marked (e.g. fruit) it is appropriate to mark the outer container with the country of origin.

- For example, goods originating in China should be marked "Made in China".

- The marking must be legible and permanent enough for the ultimate purchaser to be made aware of the goods origin.
Personal Protective Equipment

Occupational Safety and Health Administration

- PPE eyewear is regulated by Occupational Safety and Health Administration (OSHA) according to **29 CFR 1910 Subpart I**
- FDA does not regulate industrial safety eyewear unless you also make sunglass claims or if the eyewear is Rx.
- If the eyewear is claimed as being sunglasses or Rx frame, it is regulated by FDA regulation as Medical Device 510 (K)
- PPE eyewear regulated by OSHA can be self-certified to the standard **ANSI/ISEA Z87.1** American National Standard for Occupational and Educational Personal Eye and Face Protection Devices
Personal Protective Equipment

Regulations

- OSHA 29 CFR 1910 Subpart I – Personal Protective Equipment

- § 1910.132 General requirement

- § 1910.133 Eye and face protection

- § 1910.134 Respiratory protection

- § 1910.135 Head protection

- § 1910.136 Foot protection

- § 1910.137 Electrical protective equipment

- § 1910.138 Hand protection

- § 1910.139 [ Reserved ]

- § 1910.140 Personal fall protection system

- Appendix A to Subpart I of Part 1910 – Reference for Further Information (Non-mandatory)

- Appendix B to Subpart I of Part 1910 – Nonmandatory Compliance Guidelines for Hazard Assessment and Personal Protective Equipment Selection

- Appendix C to Subpart I of Part 1910 – Personal Fall Protection Systems Non-Mandatory Guidelines

- Appendix D to Subpart I of Part 1910 – Test Methods and Procedures for Personal Fall Protection System Non-Mandatory Guideline
ANSI/ISEA Z87.1:2015

The Scope of This Standard

- This standard sets forth criteria related to the general requirements, testing, permanent marking, selection, care, and use of protectors to minimize the occurrence and severity or prevention of injuries from such hazards as impact, non-ionizing radiation and liquid splash exposures in occupational and educational environments including, but not limited to, machinery operations, material welding and cutting, chemical handling, and assembly operations.

Types of eye-protectors applicable for this requirement:

- Spectacles with or without lateral protection
- Goggles
- Face-shields
PPE Goggles and Face Shields

Testing Items

Mandatory Items:

- Optical Requirements
  - Luminous transmittance
  - Haze
  - Refractive powers

- Physical Requirements
  - Drop ball
  - Ignition
  - Corrosion on metal parts
  - Minimum coverage area

- Other Requirements
  - Goggles ventilation

Other Claimed and Optional Items

- Impact requirement for goggles claimed impact-rated >> marking with “Z87.1 +”
  - Lateral protection
  - High mass impact
  - High velocity impact

- If the lenses are with filtering function:
  - Table 6 transmittance requirement for welding filters
  - Table 7 transmittance requirement for ultraviolet filters
  - Table 8 Transmittance requirement for infrared filters
  - Table 9 Transmittance for visible light.
  - Table 10 Transmittance requirement for special-purpose filters

- Other Optional Items
  - Droplet and splash hazard
  - Dust hazard
# Marking of PPE Goggles and Face Shields

## Table 3. Marking Requirements

<table>
<thead>
<tr>
<th>Type of Mark</th>
<th>Lenses &amp; Replacement Lenses</th>
<th>Frame(^1)</th>
<th>Marking for Complete Device (no replaceable components)(^2)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Spectacles</td>
<td>All Other</td>
<td></td>
</tr>
<tr>
<td>Manufacturer’s Mark or Logo</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Standard</td>
<td>Z87</td>
<td>Z87</td>
<td>Z87</td>
</tr>
<tr>
<td>Plano, Readers, Magnifiers</td>
<td>Z87</td>
<td>Z87-2</td>
<td>Z87-2</td>
</tr>
<tr>
<td>Rx</td>
<td>H</td>
<td>H</td>
<td></td>
</tr>
<tr>
<td>Coverage (small head sizes)(^3)</td>
<td>H</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Impact Mark</td>
<td>+</td>
<td>Z87+</td>
<td>Z87+</td>
</tr>
<tr>
<td>Impact Rated Plano, Readers Magnifiers</td>
<td>+</td>
<td>Z87+</td>
<td>Z87-2+</td>
</tr>
<tr>
<td>Impact Rated Rx</td>
<td>+</td>
<td>Z87+</td>
<td>Z87-2+</td>
</tr>
</tbody>
</table>

## Impact Mark

- Impact Rated Plano, Readers Magnifiers
- Impact Rated Rx

## Lens Type

- Clear
- Welding Filter (see table 5)\(^4\)
- UV Filter (see table 6)\(^4\)
- Visible Light Filter (see table 8)\(^4\)
- IR Filter (see table 7)\(^4\)
- Variable Tint
- Special Purpose Lenses

## Use

- Splash / Droplet
- Dust
- Fine Dust

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\(^1\) Complete device to include lenses and frame.

\(^2\) Complete device to include lenses, frame and any replaceable components.

\(^3\) Combination of small head sizes is sold as a single unit.

\(^4\) Lenses specified in tables 5, 6, 7, and 8 are “impact rated” and do not require the use of the “Impact Rated” symbol.
2020/2021 Updates for Testing Standards

Draft International Standard – Published in August 2018

ISO/DIS 16321-1 Eye and face protection for occupational use – Part 1:
General Requirements
➢ Application similar to EN 166 + EN 170 + EN 171 + EN 172

ISO/DIS 16321-2 Eye and face protection for occupational use – Part 2:
Additional Requirements for protectors used during welding and related techniques
➢ Application similar to EN 166 + EN 169

ISO/DIS 16321-3 Eye and face protection for occupational use – Part 3:
Additional Requirements for mesh protectors
➢ Application similar to EN 1731
2020/2021 Updates for Testing Standards

Draft International Standard – Published in August 2018

ISO/DIS 18527-1 Eye and face protection for sports use – Part 1:
Requirements for downhill skiing and snow-boarding goggles
➢ Application similar to EN 174 + EN 13178

ISO/DIS 18527-2 Eye and face protection for sports use – Part 2:
Requirements for eye protectors for squash and eye protectors for racquetball and squash
➢ No similar application to ISO standard
➢ Application similar to ASTM F803
2020/2021 Updates for Testing Standards

Draft International Standard – Published in August 2018

Test methods related to ISO/DIS 16321-1, ISO/DIS 16321-2 & ISO/DIS 16321-3

ISO 18526-1:2020 Eye and face protection – Test methods
  ➢ Part 1: Geometrical optical properties

ISO 18526-2:2020 Eye and face protection – Test methods
  ➢ Part 2: Physical optical properties

ISO 18526-3:2020 Eye and face protection – Test methods
  ➢ Part 3: Physical and mechanical properties

ISO 18526-4:2020 Eye and face protection – Test methods
  ➢ Part 4: Headforms
2020/2021 Updates for Testing Standards

New US Standards – Launched in April 2020

- ANSI/ISEA Z87.1:2020 – Occupational and Educational Face and Eye Protection

- ANSI Z80.3:2018 – Nonprescription Sunglasses and Fashion Eyewear requirements due for 2020 revision

- ANSI Z80.1:2015 – Prescription Ophthalmic Lenses due for 2020 revision

- ANSI Z87.62 – Bio-Hazard Eye and Face Protection
  - New group writing a standard for healthcare workers
  - Initial draft due in June with plans to publish in 2020
Thank You!

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