



The Italian Institute for the Certification of Optical Products



## **CERTOTTICA**

Z.I. Villanova, 7 • 32013 Longarone (BL)

Tel. +39.0437.573157 • Fax +39.0437.573131

info@certottica.it • marketing@certottica.it • www.certottica.it

## ABOUT CERTOTTICA

Certottica is a laboratory with a long experience. Its aim is supporting the eye-wear companies during the marketing process of optical products, according to European Regulations, applying International technical standards.

**Certottica:**

- evaluates the EC conformity of all Personal Protective Equipment of eyes of I Category, such as:
  - sunglasses;
  - ski goggles;
  - swimming goggles.
- evaluates the EC conformity for some kind of Medical Devices of I category of the eyes, such as:
  - spectacles frames;
  - ready-to-wear spectacles;
  - ophthalmic lenses.
- issues test reports which support the manufacturers' technical documenta-

tion and declaration of conformity.

- issues EC Type-Examination according to the European Regulation for the Personal Protective Equipment of II and III category, such as:
  - safety eyewear;
  - face shield;
  - motorcycle goggles.

Each year, Certottica undertakes to have its laboratory tests accredited by Accredia, the only National Accreditation Body for the testing laboratories.

Having laboratory tests always updated and accredited means that test reports are internationally recognized by all the States belonging to the Mutual Recognition Arrangements (MRA). This agreement has been drawn up with all the national accreditation institutes and it is included in the National Association of Testing Authorities (NATA) accreditation system.



## PERSONAL PROTECTIVE EQUIPMENT

Personal Protective Equipment (PPE) is regulated by the European Regulation (EU) 2016/425: PPE is any device or item which is worn or held by a person in order to be protected against one or more risks which could jeopardize his/her health and safety.

The PPE shall be classified according to the risk categories as follows:

**Category I PPE:** simple device, since the users can evaluate their efficiency in the protection against minimum risks. Some examples: sunglasses, ski and swimming goggles.

**Category II PPE:** devices not classified in the I and III PPE categories. Some examples: safety eyewear, face shield, motorcycle goggles.

**Category III PPE:** PPE falling under this category includes exclusively the risks that may cause very serious consequences such as death or irreversible damage to health.

**The reference standards for PPE are:**

- EN 166 "Personal eye-protection – Specifications";
- EN 167 "Personal eye-protection – Optical test methods";
- EN 168 "Personal eye-protection – Non-optical test methods";
- EN 169 "Personal eye-protection – Filter for welding and related techniques – Transmittance requirements and recommended utilisation";
- EN 170 "Personal eye-protection – Ultraviolet filters – Transmittance requirements and recommended use";
- EN 171 "Personal eye-protection – Infrared filters – Transmittance requirements and recommended use";
- EN 172 "Personal eye-protection – Sunglare filters for industrial use";



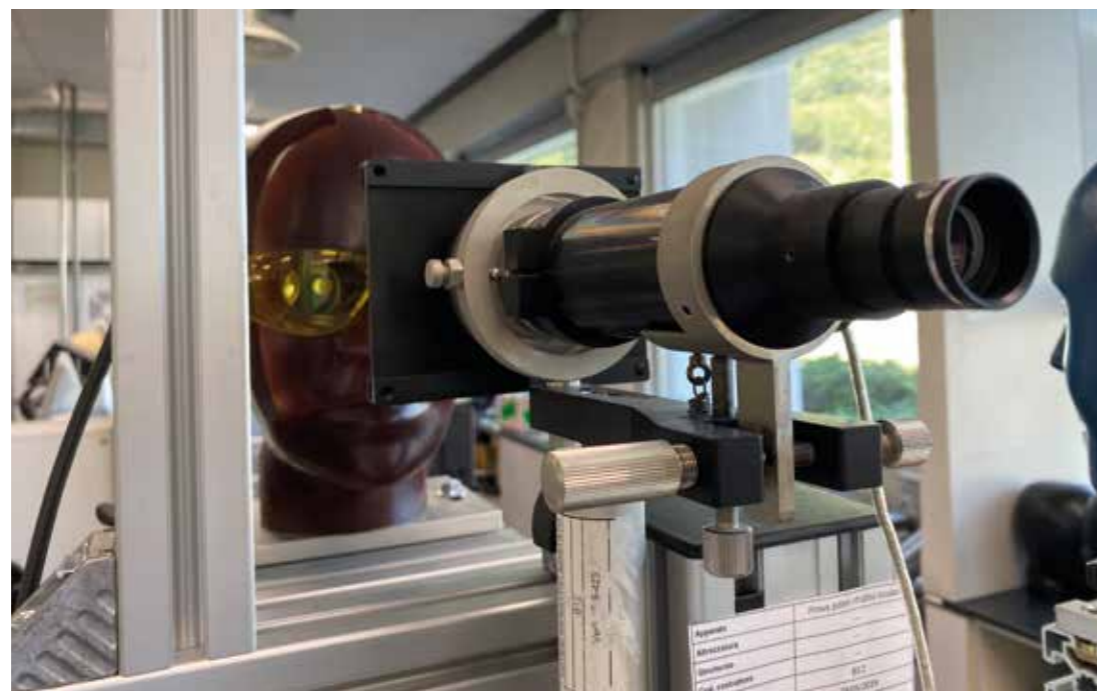
- EN 174 “Personal eye-protection - Ski goggles for downhill skiing”;
- EN 175 “Personal protection – Equipment for eye and face protection during welding and allied processes”;
- EN 1731 “Personal eye protection – Mesh eye and face protectors”;
- EN 1938 “ Personal eye-protection – Goggle for motorcycle and moped users”;
- EN 13178 “Personal eye-protection – Eye protectors for snowmobile users”;
- ISO 12312 “Eye and face protection—Sunglasses and related eyewear – Part 1: Sun-glasses for general use”.
- AS/NZS 1337 .1 “Personal eye protection Part 1: Eye and face protectors for occupational applications”
- AS/NZS 1338.1 “Filters for eye protectors - Part 1: Filters for protection against radiation generated in welding and allied operation”
- AS/NZS 1338.2 “Filters for eye protectors - Filters for protection against ultraviolet radiation”
- CSA Z94.3 “Eye and Face Protectors”
- EN 16805 “Diving Equipment – Diving Mask – Requirement and test methods”;
- BS 5883 “Specification for Surface swimming goggles”.

**Other extra European specifications:**

- ANSI Z80.3 “Ophthalmic – Non-prescription Sunglasses and Fashion Eyewear – Requirements”;
- ANSI Z87.1 “Occupational and educational personal eye and face protection device”;
- ASTM F 659 “Standard Specification for Skier Goggles and Faceshields”;
- AS/NZS 1067 “Sunglasses and fashion spectacle.

**Particular specification (impact tests on eye protector):**

- MIL-PRF-31013 “Spectacles, special protective eyewear cylindrical system;
- MIL-STD-662F “V50 ballistic test for armour”;
- STANAG 2920 “Ballistic test method for personal armour materials and combat clothing”;
- STANAG 4296 “Eye protection for the individual soldier - Ballistic protection”.



## MEDICAL DEVICE

Medical Device is regulated by the European Regulation (EU) 2017/745. Ophthalmic lenses, spectacle frames and ready eyewear are class I Medical Device.

Certottica tests and issues test reports on all type of spectacle and ophthalmic lenses for pre-scription and ready to wear Medical Devices equipment.

**The different types of equipment that Certottica can test are:**

- Spectacles;
- Ready to wear spectacles;
- Single vision lenses;
- Multifocal lenses;
- Power variation lenses.

**The reference standards are:**

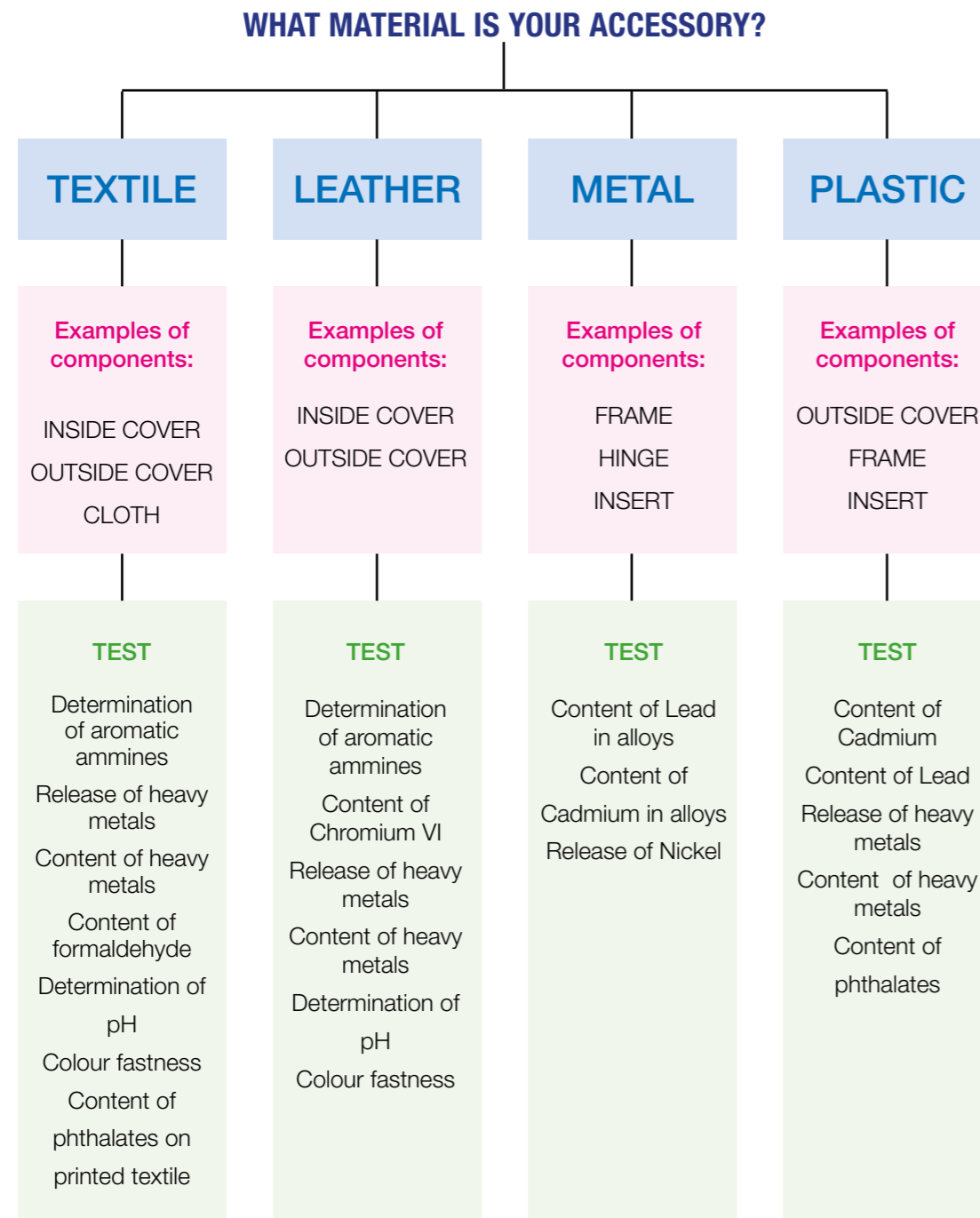
- ISO 12870 “Ophthalmic optics – Spectacle frames – Requirements and test methods”;
- ISO 8980-1 “Ophthalmic optics – Uncut finished spectacle lenses – Part 1: Specifications for single-vision and multifocal lenses”;
- ISO 8980-2 “Ophthalmic optics – Uncut finished spectacle lenses – Part 2: Specifications for power-variation lenses”;
- ISO 8980-3 “Ophthalmic optics – Uncut finished spectacle lenses – Part 3: Transmittance specifications and test methods”;
- ISO 8980-4 “Ophthalmic optics – Uncut finished spectacle lenses – Part 4: Specifications and test methods for antireflective coatings”;
- ISO 8980-5 “Ophthalmic optics – Uncut finished spectacle lenses – Part 5: Minimum requirements for spectacle lens surfaces claimed to be abrasion-resistant”;
- EN 14139 “Ophthalmic optics Specifications for ready-to-wear spectacles”;
- ISO 16034 “Ophthalmic optics - Specifications for single-vision ready-to-wear nearvision spectacles”.
- ISO 21987 “Ophthalmic optics - Mounted spectacle lenses”



## CHEMICAL ANALYSIS ON THE PRODUCTS

Textiles and leather must respect the safety standards set out by regulations, just like the other frame components. Therefore, they must undergo chemical tests to check their compliance with the necessary requirements.

In order to meet companies needs, Certottica laboratory has prepared a series of analyses to be carried out on TEXTILES, both natural and man-made ones, on LEATHER, PLASTIC and METAL components, in order to assess there are no health hazardous substances in the products.



### AZO DYES

**Use:** they are among the most used colouring agents in the textile and leather sectors.

**Toxicity:** some azo dyes, in case of cutaneous absorption or ingestion, release within the body of the substances known with the name of aromatic amines, some of which are carcinogenic.

**Restrictions:** the REACH regulation sets a concentration limit of 30 ppm for 22 aromatic amines recognized as carcinogenic in textiles and leather subject to direct and prolonged contact with the skin.

### FORMALDEHYDE

**Use:** it is an organic substance used in textile manufacturing processes at finishing stage, when washing natural fibres, in anti-crease resins, in easy-care finishing products, in colouring fixers, in binders for pigment printing and as anti-mould and stabilizing agent.

**Toxicity:** it is a known carcinogenic agent, classified in category 1B of the REACH Regulation (Annexe XIV) since 2014, and it is highly irritating if inhaled and can cause dermatopathies.

**Restrictions:** voluntary, with reference to the limits set in the Eco-label, Oeko Tex.

### HEXAVALENT CHROMIUM

**Use:** it can be found in leather as residue of the leather tanning process. Its presence in tanning can be avoided but, trivalent Chromium salts (non allergenic) which are necessary in this manufacturing step, are often replaced with hexavalent Chromium salts, which are cheaper.

**Toxicity:** it is classified as carcinogen of class 1A. Moreover, it can cause very serious contact allergies, also in very low concentrations.

**Restrictions:** since may 1st 2015 it is subject to a new restriction introduced by Annexe XVII of the REACH Regulation for leather goods and their parts. The limit for items which come into contact with the skin is 3mg/kg (0,0003% in weight) on the overall dry leather weight.

### PHTHALATES

**Use:** are the most widely used additives to make plastic soft and flexible (PVC is the main plastic material in which they are used). In textiles they are used to make prints or other soft plastic elements. In leather they can be used in the finishing stage of tanned leather.

**Toxicity:** some of the phthalates on the market are classified as endocrine disruptors.

**Restrictions:** a limited number of phthalates (DBP, BBP, DEHP, DIBP, DINP, DNOP, DIDP) is subject to European restrictions (point 51 and 52 of Annexe XVII of the REACH Regulation): their use is not permitted in concentrations of over 0.1% in toys and items for children. Limitations will be applied also to other compounds of the phthalates class, already part of the ECHA Candidate List (list of the substances of very high concern candidate to authorization). From 25 April 2018, the American Commission CPSIA restricted three additional phthalates in toys and childcare articles in concentrations above 0.1%.

### NICKEL

**Use:** employed to coat other metals for decoration purposes (it gives the product excellent shine and brightness) and functional ones (it makes the item surface more durable, more resistant to deterioration, to aging, to oxidizing and corrosive attacks and to wear).

**Toxicity:** classified as possible carcinogen for humans (class ARC 2B) and it can cause serious allergies due to contact of the metal with the skin.

**Restrictions:** the REACH Regulation in Annexe XVII, point 27, sets a limit of 0.5 micrograms per

square centimetre per week to Nickel release for jewellery and costume jewellery items and to other objects which come into contact with the skin.

### LEAD

**Use:** it is added on purpose, as impurity or as additive for metallic alloys (in particular brass), as pigment and as stabilizer in polymers (in particular in PVC).

**Toxicity:** it can interfere with the enzymatic activity and interact with important structures such as RNA and DNA. Exposure to this metal is particularly harmful for the development of children.

**Restrictions:** the REACH Regulation in Annexe XVII forbids the marketing of items, which can be put into the mouth by children, having a lead concentration (expressed in metal) equal or above 0.05% in weight. Lead is also present in the Candidate list, therefore its concentration in the article must not exceed the limit of 0.1% in weight.

### CADMIUM

**Use:** employed for the cadmium-plating process, which is used to protect other materials such as steel, copper and iron from corrosion. It can be used also in the manufacturing of special alloys or be employed as colouring pigment in paints.

**Toxicity:** it is highly toxic, it has teratogenic and carcinogenic effects, it replaces zinc in many “metal-enzyme” complexes and it tends to accumulate in kidneys, liver and other organs.

**Restrictions:** the REACH Regulation in Annexe XVII sets strict limits for the presence of Cadmium in items made with plastic (< 0.01 % in weight of the plastic), in painted items (< 0.1 % in weight of the metal). Cadmium is present in the Candidate list, therefore its concentration in the article must not exceed the limit of 0.1% in weight.

### OTHER HEAVY METALS

**Use:** they can be found in textiles and leather as manufacturing residues (e.g. dyeing, finishing, tanning)

**Toxicity:** Some heavy metals are classified as carcinogens and allergens and have bioaccumulation properties (once absorbed by the body they tend to accumulate in internal organs such as the liver or kidneys) The highest toxicity metals are Nickel (Ni), Lead (Pb), Cadmium (Cd), Antimony (Sb), Arsenic (As), Chromium (Cr), Mercury (Hg), but also Cobalt (Co), Manganese (Mn), Copper (Cu), Selenium (Se), Zinc (Zn) can be harmful for the body in high concentrations. Particular attention must be paid to the presence of heavy metals in objects for children.

**Restrictions:** the REACH Regulation sets specific limits for the most used heavy metals at industrial level such as Lead, Cadmium and Nickel.

### QUALITATIVE TEST: PH AND COLOUR FASTNESS

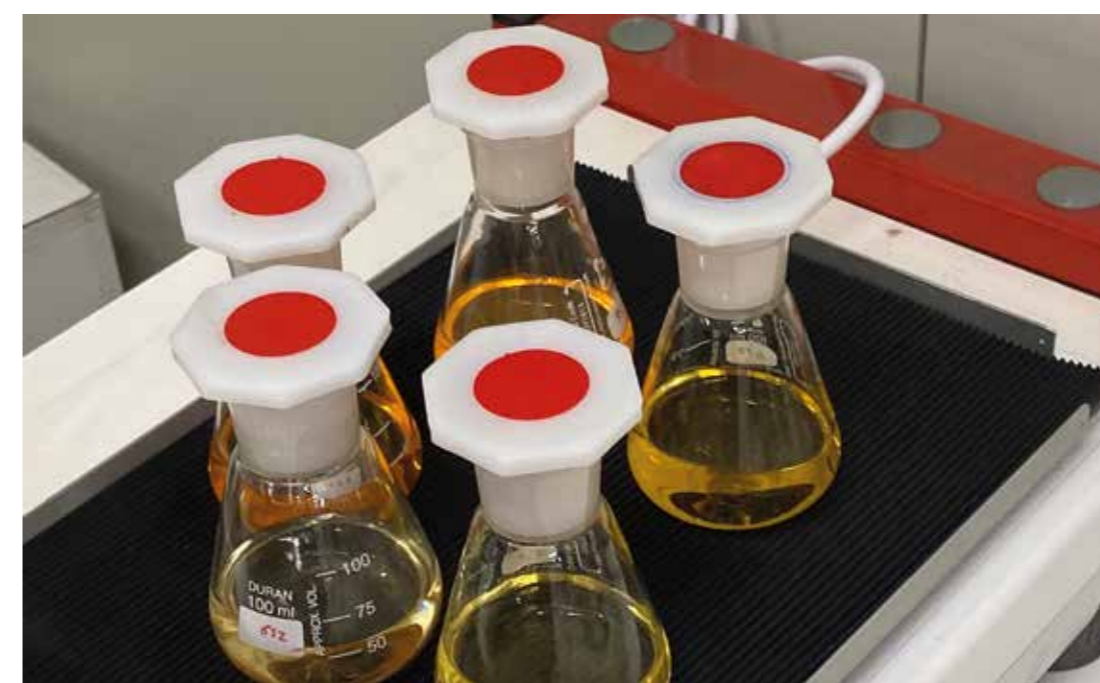
Determining the pH of the aqueous extract of textiles and leathers is a parameter which shows the material skin compatibility. The samples with pH values outside the range of acceptability, near to the “eudermic” pH value, may potentially trigger allergic or inflammatory reactions in sensitive subjects. Moreover, pH alterations are a useful indicator of the residual effects caused by processing and of the quality of the post-dyeing treatments which, when correctly performed, guarantee the neutralization of the excess alkalinity or acidity found in textiles and leather goods. For colour fastness means the resistance of the colour of textiles and leathers for different alteration agents to which they may be exposed. The color degradation of the material and unloading on the uncolored reference textile are a good indicator to check the tightness of colors in textiles and leathers.

### PLASTIC CHEMICAL TESTS

Material	Substance	Method
Plastic	Cadmium	EN 1122
	Lead	CPSC-CH-E1002-08.3
	Heavy metals release in items for children under 36 months	Internal method in compliance with EN 71-3
	Heavy metals content	Internal method in compliance with CPSC-CH-E1002-08.3
	Phthalates	CPSC-CH-C1001-09-4

### METAL CHEMICAL TESTS

Material	Substance	Method
Metal	Cadmium	Internal method in compliance with CPSC-CH-E1001-08.3
	Lead	CPSC-CH-E1001-08.3
	Nickel Release	EN 1811 (articles intended to come into direct and prolonged contact with the skin)  EN 16128 (spectacle frame and sunglasses)



## LEATHER CHEMICAL TESTS

Material	Substance	Method
Leather	AZO-arylamines	ISO 17234
	Chromium VI	ISO 17075-1
	Heavy metals release in items for children under 36 months	Internal method in compliance with EN 71-3
	Heavy metals content	ISO 17072-2
	Heavy metals release	ISO 17072-1
	Formaldehyde	ISO 17226-2
	PH	ISO 4045
	Colour fastness	ISO 11642

## TEXTILES CHEMICAL TESTS

Material	Substance	Method
Textiles-Natural or Man-made Fibres	AZO-arylamines	ISO 14362
	Heavy metals release in items for children under 36 months	Internal method in compliance with EN 71-3
	Heavy metals release	EN 16711-2
	Heavy metals content	EN 16711-1
	Formaldehyde	ISO 14184
	Phthalates	ISO 14389
	PH	ISO 3071
	Colour fastness	ISO 105-E04

### The reference standards are:

- EN 1122:2002 "Plastics - Determination of cadmium - Wet decomposition method"
- CPSC-CH-E1001-08.3 "Total Lead in Metal"
- CPSC-CH-E1002-08.3 "Standard Operating Procedure for determining total Lead (Pb) in non-metal children's products"
- CPSC-CH-E1003-09.1 "Standard Operating Procedure for determining total Lead (Pb) in Paint and Other Similar Surface Coatings"
- EN16128 "Ophthalmic optics: Reference method for the testing of spectacle frames and

sunglasses for nickel release"

- EN 1811:2011+A1:2015 - Reference test method for release of nickel from all post assemblies which are inserted into pierced parts of the human body and articles intended to come into direct and prolonged contact with the skin.
- CPSC-CH-E1001-09.4 "Standard Operating Procedure for determination of phthalates"
- ISO 17234-1 "Chemical test of determination of certain azo colourants in dyed leathers"
- ISO 17075-1 "Leather: Determination of Chromium (VI) content"
- ISO 17072-1 "Leather: Chemical determination of metal content-Part 1: Extractable metals"
- ISO 17072-2 "Leather: Chemical determination of metal content-Part 2: Total metal content"
- EN16711-1 "Textile: Determination of metal content- Part 1 : Determination of metals using microwave digestion"
- EN16711-2 "Textile: Determination of metal content- Part 2 : Determination of metals extracted by acidif artificial perspiration solution"
- ISO 17226-2 "Leather: Chemical determination of formaldehyde content-Part 2: method using colorimetric analysis"
- ISO 4045 "Leather: Chemical test of determination of pH"
- ISO 11642 "Leather: Tests for colour fastness – Colour fastness to water"
- ISO 14184-1 " Textiles: Determination textiles of formaldehyde - Part 1: Free and hydrolysed formaldehyde (water extraction method)"
- ISO 14362-1 " Textiles: Methods for determination of certain aromatic amines derived from azo colorants - Part 1: Detection of the use of certain azo colorants accessible with and without extracting the fibres"
- ISO 3071 " Textiles: Determination of pH of aqueous extract"
- ISO 105 E04 "Textiles-Test for colour fastness. Part E04: Colour fastness to perspiration"

### Other Specifications:

- ISO 9227: "Corrosion tests in artificial atmospheres"
- ASTM G 154-06: "Standard Practice for Operating Fluorescent (UV) Lamp Apparatus for Exposure of Nonmetallic Materials"





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