EUROPEAN STANDARDS FOR PPE

2016/425 (EU) is the European Regulation covering the manufacture and sale of PPE into Europe. This superceded the PPE Directive 89/686/EEC in April 2018, however the certificates for products manufactured in accordance with the directive whilst it wa was in force are valid until 21st April 2023.

CE CATEGORY

European Regulation 2016/425 (EU)



CAT I Minor Risk

CAT II Reversible Risks (injury), certified compliant by a notified body.

CAT III Irreversible Risks certified compliant by a notified body. Also subject to ongoing surveillance by a notified body whose number is specified.

EN 420:2003+A1:2009

General requirements and test methods

- Technical information*
- Glove markings
- Sizes
- Level of dexterity (1 to 5)
- Innocuousness of the glove

* Printed on the packaging or on the user instruction. For further details, contact your distributor or visit our website www.globus.co.uk



EN388:2016

Mechanical risks



a) ABRASION RESISTANCE (0-4)

Number of cycles required to abrade a hole using abrasive paper in a circular sample of glove material under constant pressure and motion.

b) BLADE CUT RESISTANCE BY COUP TEST (0-5)

Number of cycles required to cut a sample using a stainless steel circular blade under constant speed and low force of 5 newton (approx. 510g). For materials that dull the blade, after a certain number of cycles without cut through, the ISO 13997 test is performed and becomes the reference cut resistance value.

c) TEAR RESISTANCE (0-4)

Force required to propagate a tear in a rectangular sample of a glove with a starting incision, to a maximum force of 75N (approx. 7,6kg).

d) PUNCTURE RESISTANCE (0-4)

Force required to puncture the sample with a standard size steel point at a constant speed of 10 cm/min.

e) BLADE CUT RESISTANCE BY ISO TEST (A-F)

Force in newton (N) required to cut through a sample using a rectangular blade in a specified cut test machine such as Tomodynamometer (TDM). This test is optional unless the blade in Coup test becomes dull, whereupon it becomes the reference for cut resistance. A letter value is assigned as follows:

Level of Protection	Α	В	С	D	E	F
Force in newton	> 2	≥5	≥10	≥15	≥22	≥30

f) IMPACT RESISTANCE (P)

For protective gloves claiming impact resistance. Measures dissipation of force by the area of protection upon an impact of a domed anvil at an impact energy of 5 joules. Testing is carried out in accordance with the impact protection test for motorcycle protective gloves of EN 13594:2015 standard. A letter "P" is added on successful pass, while a fail remains unmarked. Level X can also be applied for a – f above, which means "not tested".

Level of Protection	Α	В	С	D	E
Abrasion resistance (number of cycles)	>100	≥500	≥2000	≥8000	-
Blade cut resistance by Coup test (index)	>1,2	≥2,5	≥5	≥10	≥20
Tear resistance (force in newton)	>10	≥25	≥50	≥75	-
Puncture resistance (force in newton)	>20	≥60	≥100	≥150	-

EN 16523-1:2015

(replaces EN 374-3) Resistance to chemical permeation





Until 21/04/2018

Test method to measure the resistance of the PPE material to permeation by hazardous chemicals at molecular level and under continuous contact. The resulting value is the breakthrough time or the time needed by the hazardous liquid or gas to get in contact with the skin. The glove is classified in terms of breakthrough time performance level 1 to 6.

The standard defines a list of 18 chemicals.
The minimum breakthrough time for a Type
A glove is 30 mins (Level 2) for 6 chemicals,
for a Type B it is 30 mins for at least 3
chemicals, and for Type C it is 10 mins (Level
1) for at least 1 chemical on the list.

The 'chemical resistant' glove pictogram must be accompanied by code letters for the tested chemicals for Type A and Type B gloves. Type C marked gloves are without any code letter.

Measured breakthrough time	Permeation performance index
> 10	1
> 30	2
> 60	3
> 120	4
> 240	5
> 480	6

Type of gloves	Breakthrough time
Α	≥30 min for at least 6 chemicals
В	≥30 min for at least 3 chemicals
С	≥10 min for at least 1 chemical







From 21/04/2018

List of chemicals:

Code	Chemical	CAS Number	Class
Α	Methanol	67-56-1	Primary alcohol
В	Acetone	67-64-1	Ketone
C	Acetonitrile	75-05-8	Nitrile compound
D	Dichloromethane	75-09-2	Chlorinated paraffin
Е	Carbone disulphide	75-15-0	Organic compound containing sulphur
F	Toluene	108-88-3	Aromatic hydrocarbon
G	Diethylamine	109-89-7	Amine
Н	Tetrahydrofurane	109-99-9	Heterocyclic ether
1	Ethyl acetate	141-78-6	Ester
J	N-Heptane	142-85-5	Saturated Hydrocarbon
K	Sodium hydroxide 40%	1310-73-2	Inorganic base
L	Sulphuric acid 96%	7664-93-9	Inorganic mineral acid
M	65% Nitric acid	7697-37-2	Inorganic mineral acid, oxidizing
N	99% Acetic acid	64-19-7	Organic acid
0	25% Ammonium hydroxide	1336-21-6	Organic base
Р	30% Hydrogen peroxide	7722-84-1	Peroxide
S	40% Hydrofluoric acid	7664-39-3	Inorganic mineral acid, contact poison
Т	37% Formaldehyde	50-00-0	Aldehyde

EN 374-4:2013

Resistance to chemical degradation

Degradation is the deleterious change in one or more properties of a protective glove material due to contact with a chemical. Indications of degradation can be delaminating, discoloration, hardening, softening, dimensional change, loss of tensile strength, etc. It is determined by measuring the percentage change in puncture resistance of the glove material after a continuous contact for 1 hour of the external surface with the challenge test chemical. The results of the degradation test must appear in the information leaflet for all three glove types.

EN ISO 374-5:2016

Protection against micro-organisms

EN ISO 374-5 EN ISO 374-5





Micro-organisms are defined by the standard as bacteria, fungi or viruses. To claim resistance to bacteria and fungi the glove must pass the penetration resistance test according to standard EN 374-2: 2014. If the glove passes ISO 16604: 2004 (method B) test it can claim resistance to viruses as well, and the term "VIRUS" will be added below the biohazard pictogram.

EN ISO 374-1:2016

The standard defines requirement the capability of gloves to protect the user against penetration, permeation and degradation by chemicals and microorganisms. It classifies three types of gloves by level of protection (A, B, and C) using test method EN16523-1:2015.

EN374-2:2014

Penetration resistance

The gloves must pass the air leak and/or water leak test, and meet the defined AQL inspection level. In an air leak test the interior of glove is pressurized with air and the surface is checked for holes. In a water leak test the glove is filled with water, and checked for the appearance of water droplets on the outside surface after a defined time period.

AQL (accepted quality level) is a measure of quality assurance based on random sampling procedure according to ISO 2859-1 used by manufacturers for measuring the likelihood of pinhole defects in a batch of gloves. An AQL of 1,5 accepts the statistical probability that there are less than 1,5% of the gloves with defects in the batch.

Performance level	Acceptable quality level unit	Inspection levels
Level 3	< 0,65	G1
Level 2	< 1,5	G1
Level 1	< 4,0	S4

EN407:2004

Heat-related risks



Tested levels of glove performance in terms of the following risks:

- Resistance to flammability (0 to 4)
- Resistance to contact heat (0 to 4)
- Resistance to convective heat (0 to 3)
- Resistance to radiant heat (0 to 4)
- Resistance to small splashes of molten metal (0 or 1)
- Resistance to large splashes of molten metal (0 or 1)

"0" means that during the test level 1 was not reached.

"X" means that the test was not performed or not possible.

EN511:2006

Cold-related risks



Tested levels of glove performance in terms of the following risks:

- Climatic or industrial cold transmitted by convection (0 to 4).
- Climatic or industrial cold transmitted by contact (0 to 4).
- Impermeability to water (0 or 1).

If the glove shows this symbol, it has achieved a performance index for (from left to right) climatic cold or industrial cold transmitted by convection, climatic cold or industrial cold transmitted by contact, impermeability to water.

"0" means that during the test level 1 was not reached.

"X" means that the test was not performed or not possible.

EN 1149-5:2008

Anti-static properties

Tested level of glove surface resistivity. Measured in ohms/square (Ω) , this indicates the capacity of the glove to disperse via a dissipative and/or conductive effect the accumulated static electricity discharges on the operator's hand.

RISKS RELATED TO FOOD CONTACT



It is applied to materials and articles that, at finished state, are intended to come into contact or are brought into contact with foodstuffs or with water that is for human consumption. According to Regulation 1935/2004: The materials and articles must be manufactured in accordance with good manufacturing practice so that, under normal or foreseeable conditions for their use, they do not transfer their constituents to food in quantities which could:

- Present a danger to human health,
- $\bullet \text{Results in an unacceptable change in the composition of the foodstuffs or a deterioration in the organoleptic characteristics thereof \\$

EUROPEAN DIRECTIVE 93/42/EEC

Covering medical examination and surgical gloves

EN 455-1:2000

Freedom from holes

A random sample of gloves is tested for freedom of holes by undergoing a water leak penetration test. The gloves are filled with 11 of water and must remain completely leak proof over a defined period of time. A failed test results in a higher AQL value, which for medical gloves sold in Europe must be 1,5 or lower. AQL (accepted quality level) is a quality sampling procedure ISO 2859-1 used by manufacturers for measuring the % likelihood of pinhole defects in a batch of single use gloves. An AQL of 1,5 brings a statistical probability that less than 1,5% of the gloves in the batch will have defects.

EN 455-2:2015

Physical properties

Size and tensile strength requirements for single use medical gloves.

No less than 240mm in median length and 95mm (\pm 10mm) median width to provide adequate protection along full length of the hand (exception for long cuff gloves).

Strength is measured by elongation until breaking point, indicated as Force At Break (FAB) in newton (N). FAB is measured on standard sample and on a rapid aged sample that is kept at 70°C for 7 days to simulate glove deterioration during prolonged shelf life. FAB requirements differ per glove material and if the glove is for examination or surgical purpose. Indication of median minimum FAB values:

	Force at break (N) during shelf life			
	Rubbers (e.g natural latex, nitrile)	Thermoplastics (e.g PVC, vinyl, butyl)		
Examination glove	>6.0	≥3.6		
Surgical glove	>9	-		

EN 455-3:2015

Biological evaluation

A number of important requirements are specified to maintain biological safety of the glove for the medical practitioner as well as the patient. "LATEX" pictogram on packaging for natural latex rubber gloves is mandatory. No terms suggesting relative safety of usage are permitted i.e. low allergenicity, hypoallergenicity or low protein content. Powder residue, which is seen as unwanted contaminant on medical gloves, must not exceed 2mg per glove with "powder-free" claim. Water extractable latex protein content in latex gloves must not exceed 50 microgram per gram of rubber to minimize latex exposure that can cause allergic reactions. The level of endotoxins generated by bacteria on sterile gloves that claim "low endotoxin level" may not exceed 20 EU per glove pair (EU=Endotoxin Units).

EN 455-4:2009

Shelf life determination

The standard ensures there is no performance degradation during storage period prior to use. Accelerated aging tests are performed on glove samples to determine shelf life, to enable manufacturers to prove that their product will withstand (usually) up to 3 years and in some cases up to 5 years without losing their strength and protection properties.

AMERICAN STANDARDS FOR PPE

ASTM / ANSI 105-2016



When tested in accordance with ASTM F2992-15, the glove's cut resistance shall be classified against the levels listed in Table 1, using the weight needed to cut through the material with 20 mm of blade travel.

Classification for cut resistance					
Measured breakthrough time	Permeation performance index (grams)				
A1	≥ 200				
A2	≥ 500				
А3	≥ 1000				
A4	≥ 1500				
A5	≥ 2200				
A6	≥ 3000				
A7	≥ 4000				
A8	≥ 5000				
A9	> 6000				

ANSI / ISEA 138



The performance level of the glove shall be classified against the performance levels in Table 1. The overall performance level of the glove is determined by the lowest performance level recorded.

The impact sites are located on the knuckles, the fingers and the thumb.

NOTE: For example, if the fingers and thumb are rated as performance level 1, but the knuckles are performance level 2, then the entire glove is rated as performance level 1.

Classification for impact resistance							
Performance level Mean (kN) All impacts (kN)							
1	≤ 9	< 11.3					
2	≤ 6.5	≤ 8.1					
3	≤ 4	≤5					

EN 352 Series

The requirement in relation to the ability of hearing protection products to reduce noise below daily limit levels is addressed in this standard by requiring the sound attenuation of the products, measured in accordance with EN 24869-1, to be not less than a specified minimum.

EN352 series of standards distinguish between different types of hearing protectors and each type has to comply with the respective requirements. The main types can be identified using the following extensions:

- EN 352-1:2002 applies to ear defenders
- EN 352-2:2002 applies to earplugs
- EN 352-3:2002 applies to ear defenders attached to industrial safety helmets

GUIDE TO RESPIRATORY PROTECTION STANDARDS

EN 149:2001+A1:2009

This European Standard specifies minimum requirements for filtering half masks as respiratory protective devices to protect against particles except for escape purposes. A particle filtering half mask covers the nose and mouth and chin and may have inhalation and/or exhalation valve(s). The half mask consists entirely or substantially of filter material or comprises a facepiece in which the main filter(s) form an inseparable part of the device. It is intended to provide adequate sealing on the face of the wearer against ambient atmosphere when the skin is dry or moist and the head is moved. Air enters the particle filtering half mask and passes directly to the nose and mouth area of the facepiece or via an inhalation valve(s). The exhaled air flows through the filter material and/or an exhalation valve (if fitted) directly to the ambient atmosphere. These devices are designed to protect against both solid and liquid aerosols.

Particle filtering half masks are classified according to their filtering efficiency and their maximum total inward leakage. There are three classes of devices; FFP1, FFP2 and FFP3. In addition, particle filtering half masks are classified as single shift use only, marked with symbol 'NR' or as reusable (more than one shift) – marked with symbol 'R'.

Performance tests within this Standard include filter penetration, extended exposure (loading) test, flammability, breathing resistance and total inward leakage. Reusable products are also subjected to cleaning, storage and mandatory clogging resistance tests. The clogging resistance test is optional for non-reusable products.

DOLOMITE TEST

The Dolomite test is an optional test under Standard EN 149:2001+A1:2009. Respirators which pass the dolomite clogging test are proved to provide more comfortable breathing whilst wearing the respirator and will be marked with symbol 'D' after the class of respirator, such as FFP2 NR D.

GUIDE TO PROTECTIVE CLOTHING STANDARDS



FN 14605:2005+A1:2009

Protective clothing against liquid chemicals. Performance requirements for clothing with liquid-tight, [Type 3], or liquid-tight, [Type 4], connections, including items providing protection to parts of the body only, [Types PB [3] and PB [4]].

EN 13034:2005+A1:2009

Protective clothing against liquid chemicals. Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals, [Type 6 equipment].

EN ISO 13982-1:2004+A1:2010

Protective clothing for use against solid particulates. Part 1: Performance requirements for chemical protective clothing providing protection to the full body against airborne solid particulates, [Type 5 clothing].



EN 14605:2005+A1:2009

Protective clothing against liquid chemicals. Performance requirements for clothing with liquid-tight connections, [Type 3].



EN 14605:2005+A1:2009

 $Protective\ clothing\ against\ liquid\ chemicals.\ Performance\ requirements\ for\ clothing\ with\ spray-tight\ connections,\ [Type\ 4].$



EN 13034

Protective clothing against liquid chemicals. Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals, [Type 6 equipment].



EN ISO 13982-1:2004+A1:2010

Protective Clothing for use against solid particulates. Part 1: Performance requirements for chemical protective clothing providing protection to the full body against airborne solid particulates, [Type 5 clothing]



EN ISO 14116:2015

Protective clothing. Protection against heat and flame. Limited flame spread materials, material assemblies and clothing.



EN 1149-1:2006

Protective clothing. Electrostatic properties. Part 1: Test method for measurement of surface resistivity.

EN 1149-3:2004

Protective clothing. Electrostatic properties. Part 3: Test methods for measurement of charge decay.

EN 1149-5:2008

Protective clothing. Electrostatic properties. Part 5: Material performance and design requirements.



EN ISO 20471:2013

High visibility clothing. Test methods and requirements.



EN 14126:2003

Protective clothing. Performance requirements and test methods for protective clothing against infective agents.



EN 1073-2:2002

Protective clothing against radioactive contamination. Part 2: Requirements and test methods for non-ventilated protective clothing against particulate radioactive contamination.

SIZING GUIDE - PROTECTIVE CLOTHING

PVC AND EPVC		XS	S	М	L	XL	XXL
ONLY	Height	162-168	162-168	168-174	174-180	180-186	180-186
Measurements are in cm	Chest	82-90	90-98	98-106	106-114	114-122	122-130
	Waist	74-81	81-89	89-97	97-104	104-112	112-120
	Inside Leg	73	73	76	79	81	81

ALPHACHEM X		s	M	L	XL	XXL	XXXL
ONLY	Height	164-170	170-176	176-182	182-188	188-194	194-200
Measurements are in cm	Chest	84-92	92-100	100-108	108-116	116-124	124-132

ALPHASHIELD	S	м	L	XL	XXL	XXXL
ONLY	162-170	168-176	174-182	182-188	188-194	194-200
Measurements are in cm Chest	84-92	92-100	100-108	108-116	116-124	124-132

STOCK REFERENCE CODES - PROTECTIVE CLOTHING

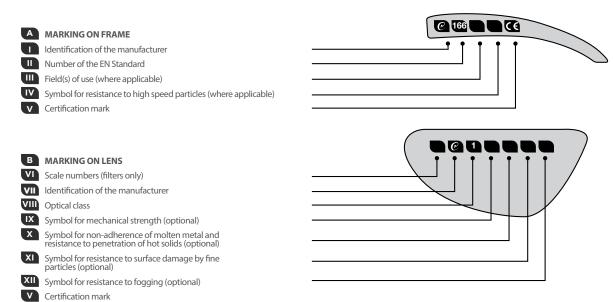
Product References:		Parts References:		EIWA	Elasticated inner wrists		
СМ	chemmaster	Α	Apron		and ankles		Example
cs	chemsol	В	Boilersuits	Н	Hood		CPBH-EW-R =
СР	chemsol plus	BB	Bib 'n' brace	J	Jackets		chemsol plus (CP)
HL	chemsol HG Lite	С	Collar	0	Glovezon 'O' ring cuff		boilersuit (B) hood (H) elasticated wrists (EW)
СН	chemsol HG	EW	Elasticated wrist	R	Reflective tape		
AG	agri Pro	EWA	Elasticated wrists and ankles	TE	(one band)		reflective tape (R)
AQ	aquasol Pro				Trousers with elasticated waist		тепесиче каре (к)

GUIDE TO EYEWEAR PROTECTION STANDARD

EN 166: 2001

EN 166:2001 is a European technical performance standard for eye protection. All manufacturers of safety eyewear are required to have their products independently tested against this European standard. Both the frame and lens are tested, therefore both must include the CE symbol and the manufacturer's logo. The CE marking certifies that a product has met EU consumer safety, health or environmental requirements.

Within the standard, there are numerous levels of compliance, depending on the end use of the piece of equipment in question.



EN 397:2012 +A1:2012

EN 397 specifies physical and performance requirements of industrial safety helmets. Helmets certified to EN 397 must meet the following requirements:

- Shock absorption
- · Resistance to penetration
- Flame resistance
- Chin-strap anchorage chin-strap releases at minimum 150N and maximum 250N

In accordance with EN 397, an industrial safety helmet may also meet the following optional requirements:

- Very low temperatures (-20 °C or -30 °C)
- Very high temperatures (+150 °C)
- Electrical insulation (440V AC)
- · Molten metal (MM)
- Lateral deformation (LD)

EN 50365:2002

EN 50365 specifies the requirements for protecting against electric shocks and preventing electric current from passing through to the head when using on low voltage installations. Helmets certified to EN 50365 must meet the following requirements:

- All helmets must meet the requirements in accordance with EN 397
- Protection against alternating voltage of up to 1000V (AC) or direct voltage up to 1500V (DC)
- Insulating helmets must not contain any conductive parts. Ventilation holes (if available) must not allow any accidental contact
 with live parts