EN Standards Explained

PPE REGULATION (EU) 2016/425

Regulation (EU) 2016/425 on personal protective equipment (PPE) has now replaced the previous Directive (89/686/EEC). The regulation details the requirements for all PPE placed on the market in the European Economic Area (EEA) to comply with the legislation. All Tilsatec PPE products have undergone examination to conform with the EU regulations and are CE marked.

CE
2834

Category I: Simple PPE

Gloves and sleeves designed to protect against minimal risks such as superficial mechanical injury and cleaning. Manufacturers are permitted to test and self certify products.

Category II: Intermediate PPE

Hand and arm protection designed to protect against cuts, abrasion, puncture and tearing. This category of products must undergo independent testing and attain certification by an accredited notified body. A CE mark will then be issued by the notified body. No item of PPE can be sold or used in the EU without being issued a CE mark. The name and address of the notified body that issued the CE mark must be present on the Instructions for Use supplied with the product. Ongoing surveillance of performance must be carried out through testing.

Category III: Complex PPE

PPE in this category includes risks that may cause very serious consequences such as death or irreversible damage to health e.g. chemicals, harmful biological agents, extreme temperatures and cuts by hand-held chainsaws. PPE must undergo independent testing and certification the same as Category II products. The quality assurance system used by the manufacturer must also be independently checked and the identification number of the notified body should appear alongside the CE mark on the Instructions for Use. Ongoing surveillance of performance and manufacturing processes must be carried out through product testing and conducting factory audits.

EN ISO 21420:2020 -
General requirements for protective gloves

Defines the general requirements for most types of protective gloves which includes:

- **Glove design and construction**
- **Sizing and measurement of gloves**
- **Cleaning**
- **Dexterity**
- **Innocuousness**
- **Product marking, packaging and information supplied by the manufacturer**
- **Breathability and comfort**
- **Electrostatic properties**

Sizing of gloves according to hand length and circumference:

Glove Size	Hand Circumference (mm)	Hand Length (mm)
4	101	<160
5	127	<160
6	152	160
7	178	171
8	203	182
9	229	192
10	254	204
11	279	215
12	304	>215
13	329	>215

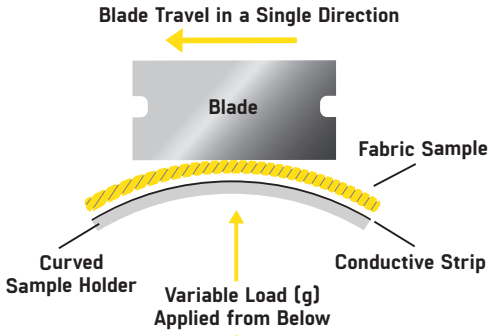
This pictogram indicates that the user should always consult the instructions for use:

EN388:2016+A1:2018 Abrasion Resistance

The Martindale Abrasion tester is used to determine the durability, wearing and abrasion of materials. The test is performed by rubbing circular specimens taken from the palm of the glove against a specified abradant. The sample holder moves in a Lissajous pattern under a 9KPa load and the test is checked at 100, 500, 2000 and 8000 cycle intervals for any signs of abrasion. Failure is confirmed once complete breakthrough of the sample is observed. Four samples are tested and the final performance level is based on the cycles at which any of the four specimens show signs of breakthrough.
The update to the EN388 standard included a change to the abradant used for this test. Only the specified type of abradant shall be used to determine the abrasion resistance.

EN ISO 13997/ASTM F2992-23 Cut Resistance

The EN ISO 13997 cut resistance method is one of the recent additions to the EN 388 standard. This test was introduced to accommodate higher cut resistance materials in the market that have a blunting effect on blades and other sharp objects. This method uses a TDM test device, fitted with a single use straight edge blade that is drawn once across the material in one direction. Once the blade cuts through the sample, the distance that the blade has travelled is recorded. (Shown right)
A range of force in newtons are used throughout the test and a graphical representation of force against cutting distance is used to determine the force required to cut through the material at 20mm of blade travel. By using the blade only once and testing a variety of load forces (as opposed to the 5N standard load used in the coupe test), the impact of blade blunting is eliminated and a more accurate representation of cut protection is assigned.



EN388:2016 Tear Resistance

A tensometer is used to determine the strength required to tear a sample apart. Four rectangular samples are tested from the palm of 4 separate gloves where two specimens with a 50mm slit in the longitudinal direction are taken across the palm, and two specimens are taken along the length of the glove. The samples are clamped in the tensometer which pulls the samples until they are fully torn apart at a speed of 100mm/min. The force at peak is recorded for each specimen tested. The minimum value achieved from all four test results is used to determine the final tear resistance level that ranges from 1 to 4.

EN388:2016 Puncture Resistance

A large 4mm wide probe with rounded stylus is pushed using a tensometer fitted with a compression load cell 50mm through the material taken from the palm of the glove at a speed of 100mm/min. Four specimens are tested and the force at peak is recorded. The minimum value achieved from all four test results is used to determine the final puncture level that ranges from 1 to 4.

ANSI/ISEA 138-19 Impact Testing

This is a new addition to the EN388: 2016+A1:2018 standard and is an optional test. It should only be included for gloves that claim specific impact resistant properties. The new impact test is based on the EN13594:2015 standard for protective gloves for motorcycle riders. The knuckle area is tested by dropping a striker with impact energy of 5J onto the test subject. To be considered a pass (P), the transmitted force needs to be less than or equal to 7 kN with no single results greater than 9 kN. Only the knuckle area is tested. While the EN standard only tests at the knuckle area, the ANSI/ISEA138-19 standard requires the testing to be carried out across 18 impact points across 2 gloves; this is 4 impact sites over the knuckles, and 5 impact sites over the fingers per glove. Unlike the EN standard that defines a pass or fail, the ANSI/ISEA138-19 test method specifies 3 performance levels. The average force measurement shall be less than or equal to 9kN for a level 1, less than or equal to 6.5kN for a level 2 and less than or equal to 4kN for a level 3. This testing is similarly carried out under an impact energy of 5J.

ASTM F278-19 Hypodermic Needle

Resistance to punctures from needlestick is measured in Newtons according to ASTM F2878:19. This standard allows the use of verified 25, 23 or 21g hypodermic medical grade needles, however the ANSI/ISEA 105-2016 standard defines the classification to be based on testing against a 25g needle.
A tensometer is used to drive the needle through the material to simulate real-life puncture hazards as closely as possible. A minimum of 12 samples are tested and the average is determined to give an accurate force required to puncture the material.

EN407:2020 - Protection from Thermal Hazards

Products certified to the new EN407:2020 standard shall be affixed with this pictogram. The pictogram accompanying EN407:2020 includes 6 digits which represent performance levels against the specific thermal tests as per the table below.

Only if a product has been tested to "Limited Flame Spread" achieving a minimum performance level of 1 then the pictogram depicting the flame shall be used.

Performance Level		1	2	3	4
a. Limited Flame Spread	After flame time	≤ 15 s	≤ 10 s	≤ 3 s	≤ 2 s
	After glow time	no requir.	≤ 120 s	≤ 25 s	≤ 5 s
b. Contact Heat	Contact temperature	100°c	250°c	350°c	500°c
	Threshold time	≥ 15 s	≥ 15 s	≥ 15 s	≥ 15 s
c. Convective heat (heat transfer delay)		≥ 4 s	≥ 7 s	≥ 10 s	≥ 18 s
d. Radiant heat (heat transfer delay)		≥ 7 s	≥ 20 s	≥ 50 s	≥ 95 s
e. Small drops molten metal (# drops)		≥ 10	≥ 15	≥ 25	≥ 35
f. Large quantity molten metal (mass)		30g	60g	120g	200g

a. Limited Flame Spread
The glove is placed vertically over a burner and is tested for ignition times 3 and 15 seconds. Classification is based on the length of time the material continues to burn and glow after the source of ignition is removed.

b. Contact Heat
The test sample is placed on a calorimeter and a heated cylinder is brought into contact with the specimen. Temperatures of 100, 250, 350 and 500oc are tested to determine the classification. The threshold time shall be calculated, where an increase in calorimeter temperature of 10oc is observed once the heated cylinder is in contact with the sample. A threshold time of greater than 15 seconds demonstrates a pass for the test temperature. If a level 3 contact heat is achieved, then limited flame spread must also be tested and pass level 1.

c. Convective Heat Resistance
The glove is placed in a controlled chamber and exposed to a flame. The resistance is based on the length of time it takes to transfer the heat from the flame. This rating can only be used if a level 3 or 4 is achieved in the limited flame spread test.

d. Radiant Heat Resistance
The glove is exposed to radiant heat and the classification is determined by how long it takes for the transfer of heat from the radiant heat source. The back of the hand is tested. This rating can only be used if a level 3 or 4 is achieved in the limited flame spread test.

e. Resistance to Small Splashes of Molten Metal
The glove is splashed with molten metal and the number of molten metal drops that are required to heat the glove to the required temperature are measured. The classification is based on the average of the number of droplets counted on four samples. Specimen are taken from the palm and the back of the glove. This rating can only be used if a level 3 or 4 is achieved in the limited flame spread test.

f. Resistance to Large Splashes of Molten Metal
The glove is lined with a skin simulated material and molten metal is poured over the glove. Once the test is complete, the liner material is assessed for any changes such as pin holing or degradation and the classification is based on the weight of molten metal required to cause the changes to the skin simulated material. If a drop of the molten metal is stuck to the glove or if the sample ignites, the material fails the test.

EN ISO 374 - Protective gloves against dangerous chemicals and micro-organisms

Gloves that are intended to protect the user against dangerous chemicals and micro-organisms shall be tested against the requirements set out in EN ISO 374-1, EN ISO 374-2 and EN ISO 374-4.
EN ISO 374-1:2016+A1:2018 defines the requirements for protection against dangerous chemicals. The standard specifies 18 chemicals to which the product may be tested against:

Code Letter	Chemical	CAS Number	Class
A	Methanol	67-56-1	Primary Alcohol
B	Acetone	67-64-1	Ketone
C	Acetonitrile	75-05-8	Nitrile Compounds
D	Dichloromethane	75-09-2	Chlorinated hydrocarbon
E	Carbon Disulphide	75-15-0	Sulphur Containing Organic Compound
F	Toluene	108-88-3	Aromatic hydrocarbon
G	Diethylamine	109-89-7	Amine
H	Tetrahydrofuran	109-99-9	Heterocyclic and ether Compound
I	Ethyl Acetate	141-78-6	Ester
J	n-Heptane	142-82-5	Saturated hydrocarbon
K	Sodium hydroxide 40%	1310-73-2	Inorganic base
L	Sulphuric Acid 96%	7664-93-9	Inorganic mineral acid, oxidising
M	Nitric Acid 65%	7697-37-2	Inorganic mineral acid, oxidising
N	Acetic Acid 99%	64-19-7	Organic acid
O	Ammonium Hydroxide 25%	1336-21-6	Organic base
P	Hydrogen Peroxide 30%	7722-84-1	Peroxide
S	Hydrofluoric Acid 40%	7664-39-3	Inorganic mineral acid
T	Formaldehyde 37%	50-00-0	Aldehyde

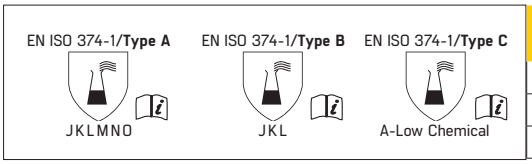
EN ISO 374 - Protective gloves against dangerous chemicals and micro-organisms

Testing is carried out on the palm of three gloves according to the standard EN ISO 16523-1:2015 'Determination of material resistance to permeation by chemicals. Permeation by liquid chemical under conditions of continuous contact'.

Performance levels are assigned as follows:

Performance Level	Measured breakthrough time (mins)
1	>10
2	>30
3	>60
4	>120
5	>240
6	>480

Gloves are categorised as **Type A, Type B** or **Type C** based on the number of chemicals they protect against and the performance level they achieve. For classes A and B, the tested chemicals shall be identified by their code letter which shall be marked under the pictogram and for class C, the tested chemical code followed by the phrase "Low Chemical" is recommended:



Type	Minimum performance level	Minimum test chemicals
A	2	6
B	2	3
C	1	1

EN ISO 374-2:2014 - Resistance to Penetration

EN ISO 374-2:2014 is the standard for the determination of resistance to penetration. This involves testing a minimum of 4 gloves for water and air leaks where all gloves must pass the testing to be able to claim chemical protection according to BS EN ISO 374-1.

The air leak test consists of applying standardised air pressure, dependent on the material thickness, to the glove interior whilst immersed in water. A leak is detected by a stream of air bubbles from the surface of the glove.

For the water leak test, the glove is filled with 1000ml of water. A leak is detected by the appearance of water droplets on the outside of the glove.

EN ISO 374-4:2019 - Degradation

For all gloves claiming chemical protection, degradation according to EN ISO 374-4:2019 must be carried out. This is determined by measuring the change in puncture resistance of the glove after continuous contact of the external surface with the challenge test chemical. All chemicals that the gloves claim protection against shall be tested for degradation and the percent change in the puncture for the glove material (degradation resistance - DR) shall be reported on the user instructions.

EN ISO 374-5:2016 - Terminology and performance requirements for micro-organisms risks

The EN ISO 374-5:2016 standard defines the requirements for gloves that protect against viruses, bacteria and fungi. Gloves claiming this standard shall pass the penetration tests described in EN ISO 374-2.

Where gloves claim protection against viruses, they shall pass additional testing according to ISO 16604:2004 - Determination of resistance of protective clothing materials to penetration by
blood-borne pathogens - Procedure B.

Marking shall be as follows for gloves tested to EN ISO 374-5:2016

Bacteria and fungi protection	Virus protection
EN ISO 374-5:2016	**EN ISO 374-5:2016**