EUROPEAN LEGISLATION AND STANDARDS

Regulation (EU) 2016/425

Why a PPE regulation?

Protective gloves are PPE (Personal Protective Equipment) and must comply with the European Regulation 2016/425 in order to freely circulate within the European Union.
The regulation 2016/425 contains the requirements that PPE must satisfy to guarantee the health and safety of the users.
That means that PPE must protect up to the required levels without compromising the user's health.
Harmonized European standards (EN 388, EN ISO 374-1 ...) are used in the certification process to assess conformity of the product to the requirements of the PPE Regulation for the risks for which the product is intended to protect.
The manufacturer must indicate the conformity of the product by CE marking it, he must also provide a EU declaration of conformity.

PPE Regulation (EU) 2016/425

This European regulation was implemented on 21 April 2018. It replaced the European Directive 89/686/EC, which was withdrawn at this same date.

Regulation (EU) 2016/425 & Directive 89/656/EEC

Regulation (EU) 2016/425 stipulates the essential health and safety requirements for designing and manufacturing PPE, as well as the responsibility of the manufacturers or importers and conformity procedures to affix the CE marking on PPE.
Directive 89/656/EEC is dedicated to the professional users of PPE. It lays down the responsibilities of the employers to supply and ensure a safe use of adequate CE-marked PPE by their employees.

CATEGORIES OF RISK AND CORRESPONDING CERTIFICATION PROCEDURE

CAT I
Minimal risks only. The manufacturer is responsible for the conformity of its products.

CAT II
Risks other than CAT 1 & CAT 3. CE-certficate of conformity obtained from a Notified Body.

CAT III
Risks causing irreversible damage to health. CE-certificate of conformity and conformity of the production from Notified Bodies.

How to read the standards?

The following pictograms, can help you understand the performance characteristics of a glove:

MECHANICAL PROTECTION

MECHANICAL HAZARDS EN 388

EN 388

4 3 4 3 C (P)

Protection against impacts (P)

From A to F
ISO 13997
cut resistance

From 0 to 4
Puncture resistance

From 0 to 4
Tear resistance

From 0 to 5
Couptest cut resistance

From 0 to 4
Abrasion resistance

LEVEL	1	2	3	4	5
Abrasion resistance (Number of cycles)	100	500	2000	8000	-
Blade cut resistance (Index)	1.2	2.5	5.0	10.0	20.0
Tear resistance (N)	10	25	50	75	-
Puncture resistance (N)	20	60	100	150	-

TEST	Level A	Level B	Level C	Level D	Level E	Level F
Straight blade cut (TDM) resistance (N)	2	5	10	15	22	30
Impact protection	Pass (P) or fail (no marking)					

*An "X" can be shown in place of any of the first 5 digits underneath the pictogram, wherethe test was either not carried out, not required or not suitable.
*The letter "P" shall be included when this test is passed. If however, the impact test is notcarried out or passed then there shall be no code letter in this sixth position (i.e. just the firstfour numbers plus the one letter for the straight blade cut test).

CHEMICAL & MICRO-ORGANISMS PROTECTION

CHEMICAL PROTECTION EN ISO 374-1

EN ISO 374-1 / TYPE A	EN ISO 374-1 / TYPE B	EN ISO 374-1 / TYPE C
U V W X Y Z	**X Y Z**	
Resistance to penetration EN 374-2 Breakthrough time ≥ 30 min for at least 6 chemicals on the list (EN 16523-1)	Resistance to penetration EN 374-2 Breakthrough time ≥ 30 min for at least 3 chemicals on the list (EN 16523-1)	Resistance to penetration EN 374-2 Breakthrough time ≥ 10 min for at least 1 chemical on the new list (EN 16523-1)

Degradation test according to EN374-4 is undertaken without performance level requirement

LETTER CODE

A Methanol	**G** Diethylamine	**M** Nitric Acid 65 %
B Acetone	**H** Tetrahydrofuran	**N** Acetic Acid 99%
C Acetonitrile	**I** Ethyl acetate	**O** Ammonia 25%
D Dichloromethane	**J** n-Heptane	**P** Hydrogen Peroxide 30%
E Carbon disulphide	**K** Sodium hydroxide 40%	**S** Hydrogen Fluoride 40%
F Toluene	**L** Sulphuric acid 96%	**T** Formaldehyde 37%

MICRO-ORGANISMS PROTECTION EN ISO 374-5

The gloves must pass the penetration resistance test EN 374-2.

EN ISO 374-5 For gloves protecting against bacteria and fungi.

If virus protection is claimed, glove has to pass ISO 16604 method B (Phi-X174 bacteriophage)

EN ISO 374-5 VIRUS For gloves protecting against bacteria, fungi and viruses.

OTHERS

RADIOACTIVE CONTAMINATION EN 421

WITH NO PERFORMANCE LEVELS

PROTECTION AGAINST PESTICIDES ISO 18889

G1 ISO 18889 Resistance to diluted pesticides/no mechanical risk

G2 ISO 18889 Resistance to diluted & concentrated pesticides/mechanical risk

GR ISO 18889 Re-entry tasks

INFORMATION PICTOGRAM EN ISO 21420:2020

The pictogram or "i" symbol shown on other pictograms indicates that user information is available and should be read.
The user information should give details of:
the supplier, glove designation, sizing, relevant standards and protection levels, limitations, listing of any known allergens contained (e.g. latex), care and cleaning instructions, shelf life if under 12 months from manufacture, relevant accessories, special transport packaging if necessary.

PROTECTION AGAINST STATIC ELECTRICITY EN 16350

ATEX environment: Vertical resistance: <108 Ω at 25% relative humidity
*The tests must be performed on 5 samples which must all pass the limit of vertical resistance

THERMAL PROTECTION

COLD HAZARD EN 511

3 2 1

0 or 1
Water permeability

From 0 to 4
Contact cold resistance

From 0 to 4
Convective cold resistance

HEAT AND FIRE EN 407

X 2 X X X X

From 0 to 4
Resistance to large quantities of molten metal

From 0 to 4
Resistance to small drops of molten metal

From 0 to 4
Radiant heat resistance

From 0 to 4
Convective heat resistance

From 0 to 4
Contact heat resistance

From 0 to 4
Limited flame spread

*X: the test does not apply or the glove has not been tested