



KIMTECH™

UNDERSTANDING GLOVE CERTIFICATION



Kimberly-Clark

PROFESSIONAL

TM



KIMTECH™

Understanding Glove Certification

Select a glove with the appropriate level of EU/UK certification to address your application risk and performance requirements.



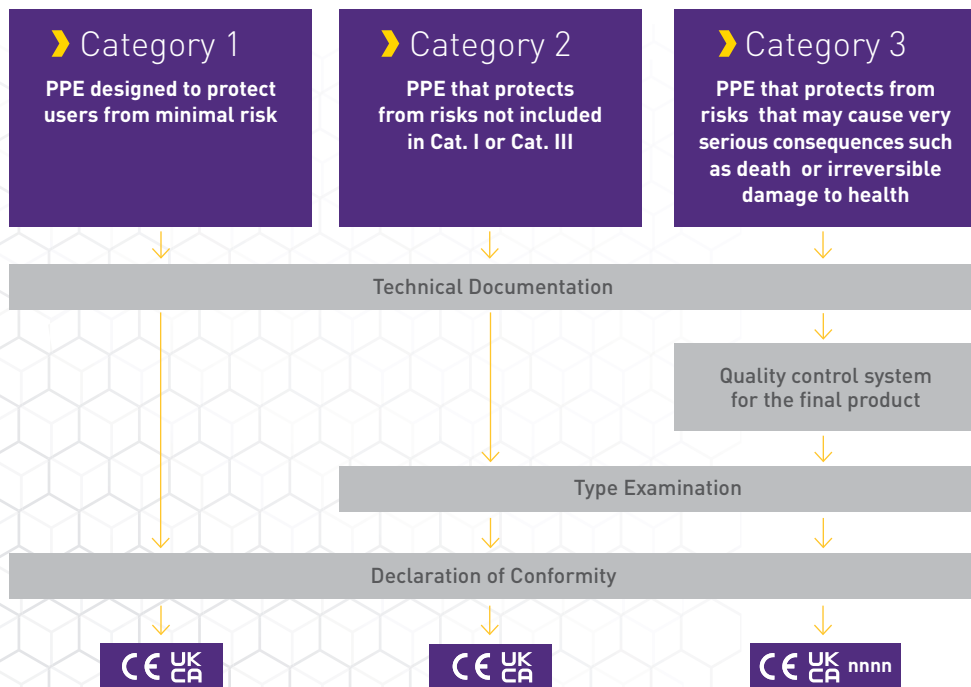
Look for CE/UKCA Certification

A Notified Body/Approved Body gives CE/UKCA certification by providing an EU/UK certificate to PPE Cat III Gloves.



To gain a CE/UKCA marking, safety protective gloves for sale in Europe/Great Britain must meet a number of stringent harmonized/ designated standards.

EU/UK Conformity Assessment*



* per PPE Regulation (EU) 2016/425 and PPE Regulation (EU) 2016/425 as brought in the UK law and amended.

PPE Category III Gloves

Protecting against risks that may cause very serious consequences (death or irreversible damage).



Look for a CE /UKCA symbol followed by the notified body/approved body number

This means that the manufacturing facility is audited and certified and a technical documentation must be completed and submitted for EU/UKCA Type Examination to a Notified Body/Approved Body.

Personal Protection

PPE Category III gloves are a minimum requirement for personal protection in applications where there is exposure to chemicals or micro-organisms. It does not mean protection against all chemicals and micro-organisms. Assess the risk and refer to glove performance data for EN374-1 and -5 test standards.

Non-Sterile Medical Gloves are considered as Class I Medical Device under the MDR (EU) 2017/745 and are self-certified. Intended use is for patient protection and other medical applications. This certification provides no standards for chemical or micro-organism protection.

*Kimtech™ gloves are only certified as Personal Protective Equipment under the PPE Regulation (EU) 2016/425.

Category III

CE0123
UKCA 0168

Must pass EU/UKCA type examination by notified body/approved body. PPE that protects from risks that may cause very serious consequences such as death or irreversible damage to health.

Provides protection against micro-organisms and chemicals. For personal protection in high risk applications

Medical Device Regulation Gloves EN455

CE

Are SELF Certified. Not submitted or EU type examination. Object is care of the patient. For Patient protection

EN STANDARDS



EN ISO 21420

Describing general standards for protective gloves:

- › Innocuousness
- › Size
- › Dexterity
- › Package marking
- › Instructions for use

EN ISO 374-1

Terminology and performance requirements for chemical risks

This standard stipulates requirements for Permeation, Penetration and Degradation for protective gloves intended to protect the users against dangerous substances.

Gloves will be categorised into three types: Type A, Type B or Type C, based on their chemical permeation performance against an extended list of chemical, which has increased from 12 to 18 :

- Type A : 6 chemicals tested with a min breakthrough time ≥ 30 min
- Type B : 3 chemicals tested with a min breakthrough time ≥ 30 min
- Type C : 1 chemical tested with a min breakthrough time ≥ 10 min
- The degradation rate according to EN 374-4 will be reported with the chemical permeation data



Product Class According to EN ISO 374-1, gloves are classified as:
Based on performance level in Type A, B or C

List of test chemicals

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 compound
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 16523-1 Determination of material resistance to permeation by chemicals -

Part 1: Permeation by potentially hazardous liquid chemicals under conditions of continuous contact

EN ISO 374-5

Protection against Micro-organisms

EN ISO 374-5 specifies the requirements and test methods for protective gloves intended to protect the user against micro-organisms.



Hand Protection - Micro-organisms hazard protection

Old Standard

EN ISO 374-2



> Level 2

EN374-2:2003 Micro-organism hazard protection against micro-organism, Level 3 - AQL 0.65 / Level 2 AQL 1.5 Test: water-tightness, ISO2859 sampling by lot.

New Standard

EN ISO 374-5



VIRUS

For protection against bacteria and fungi a penetration test is required using EN ISO 374-2. For protection against viruses, compliance to ISO 16604 (method B) standard if necessary.

EN ISO 374-4

Determination of resistance to degradation by chemicals

The resistance of a protective glove material to degradation by a liquid chemical is determined by measuring the puncture resistance change of the glove material after a continuous contact with the external surface with the challenge test chemical.

The results are expressed in % change in puncture resistance before and after.

Degradation results are reported beside each permeation breakthrough time data point as shown below:

Permeation Test EN 16523-1			Degradation Test EN ISO 374-4
Chemical	Breakthrough Time (min)	Performance Level	Performance Level %
NaOH, 40%	>480	Class 6	-15

EN 421

Protection from Radioactive Particle Contamination

To protect from radioactive contamination, the glove has to be:

- › Liquid proof and needs to pass the penetration test defined in EN ISO 374-2
- › Needs to reach at least level 1 for one of the five mechanical properties described in EN 388
- › For use in containment enclosures the glove must also pass a specific air pressure leak test
- › Materials may be modelled by their behaviour to ozone cracking. This test is optional and can be used as an aid to selecting gloves



Protection from Ionising Radiation

To protect from ionising radiation, the glove has to contain a certain amount of lead or equivalent metal, quoted as lead equivalence. This lead equivalence is marked on each glove.



EN 16350

Electrostatic Properties

For protective gloves that are intended to be worn in areas where flammable or explosive risks exist or might be present, the electrostatic properties shall be tested according to the test method described in EN 16350.

For gloves meeting the requirement in EN 16350, the corresponding pictogram can be applied.

If the surface electrostatic properties or charge decay need to be determined, EN 1149-1 or EN 1149-3 should be used to determine further electrostatic properties of the gloves. The corresponding test results may be reported in the information supplied by the manufacturer but cannot be used to apply the pictogram.



EN 388

Mechanical Protection

This European Standard specifies requirements and corresponding marking for protective gloves against mechanical risks.

- Abrasion
- Cut protection via EN ISO 13997
- Impact Protection via EN 13594
- New Marking-6 protection levels instead of 4, including a “P” code in case of impact protection

DM CUT (Levels A - F) (Via EN ISO 13997) ABRASION (Levels 1-4) ←
Level A - Light Duty Coup CUT (Levels 1-5) ←
Level B - Medium Duty TEAR (Levels 1-4) ←
Level C - Medium Duty PUNCTURE (Levels 1-4) ←
Level D - Heavy Duty TDM CUT (Levels A - F) ←
Level E - Heavy Duty (Via EN ISO 13997)
Level F - Heavy Duty



4 1 0 1 X

IMPACT
(P=
Achieved)

Level of Performance of Materials Tested With EN ISO 13997

Performance Level	Level A	Level B	Level C	Level D	Level E	Level F
TDM: Cut resistance (N)	2	5	10	15	22	30

EN 407

Thermal Hazards

This standard specifies demands and test methods for protective gloves that shall protect against heat and/or fire. The numbers given besides the pictogram indicates the gloves performance for each test in the standard. The higher number the better performance level.



1 2 3 4 5 6

- 1. Fire properties of the material <
- 2. Contact heat <
- 3. Convective heat <
- 4. Radiant heat <
- 5. Small splashes of molten metal <
- 6. Large quantities of molten metal <

EN 511

Protection Against Cold

This standard measures how well the glove can withstand both convective cold and contact cold. In addition, water permeation is tested after 30 minutes.



EN 511

1 2 1







- The first figure shows how well the glove protects against convective cold (performance level 0-4)
- The second figure shows how well the glove protects against contact cold (performance level 0-4)
- The third figure shows the glove protection against water penetration (performance 0 or 1 where 0 indicates “water penetration after 30 minutes” and 1 indicates “no water penetration after 30 minutes”)

Protection against convective cold ←

Protection against contact cold ←

Protection against water penetration ←

Kimtech™ Laboratory Gloves – Chemical Risk selection guide

	Product Code	Description	Sizing	Chemical Protection EN ISO 374-1	Biohazard Protection EN ISO 374-5	AQL	Glove Length	Chemical
	62100 - 62104	Kimtech™ Polaris™ Xtra Nitrile Gloves	XS - XL	Type B (JKOPT)	Virus	0.65	30cm	HIGHEST Chemotherapy & High Risk Applicatins CHEMICAL PROTECTION LEVEL Moderate chemical splash
	62000 - 62004	Kimtech™ Polaris™ Nitrile Gloves	XS - XL	Type B (JKOPT)	Virus	0.65	25cm	
	97610 -97614	Purple Nitrile™ Xtra™ Gloves	XS - XL	Type B (JKT)	Virus	0.65	30cm	
	90625 -90629	Purple Nitrile™ Gloves	XS - XL	Type B (JKT)	Virus	0.65	24-25cm	
	62880 - 62884	Opal™ Nitrile Gloves	XS - XL	Type B (KPT)	Virus	1.5	24cm	
	99210 -99214	Sterling™ Nitrile Gloves	XS - XL	Type C (K)	Virus	0.65	24-25cm	LOWEST Low risk - Light splash

Choosing the right glove

It is important to select gloves with the appropriate level of EU certification but don't forget to consider:

- › Lower skin allergy risk - look for synthetic materials such as nitrile instead of latex
- › Prevent skin irritation - look for Non Detectable (ND) chemical accelerator levels
- › Reduce contamination risk - ask for trend data around cleanliness
- › Ensure correct size and fit
- › Select features for performance - grip, length, dexterity, comfort, insulation



Powder free or not?



Non-latex or not?



Single Use
Only



Recyclable

Chemical Permeation Data

- Visit www.kimtech.eu, from the top menu select resources and then chemical permeation
- Select up to 4 gloves to compare. Select either breakthrough times in minutes, or classification

[illegible]

- Submit and download your PDF
- EU and UK Declarations of Conformity can be downloaded on each product detail page from www.kimtech.eu

For more information visit www.kimtech.eu

For technical assistance contact us
at kimtech.support@kcc.com

®/™ Trademarks of Kimberly-Clark Worldwide, Inc. or its affiliates. © KCWW. The colour Purple and Purple Nitrile™, the colour Grey and Sterling™ are trademarks of Owens & Minor, Inc. or its affiliates and used under license.

Publication code: 4999.01 EN 02.24