

## Manufacturer's Information

pursuant to Regulation (EU) 2016/425, Appendix II, Section 1.4. (Published in the Official Journal of the European Union)





Please read carefully before using! You are required to enclose this information leaflet when passing on the personal protective equipment, or to present it personally to the recipient. You may therefore reproduce this leaflet at your own discretion.

### Declaration of Conformity

**CE** These gloves are classified as personal protective equipment (PPE). The CE mark confirms that the product satisfies the applicable requirements of Regulation (EU) 2016/425.

### A. Markings on the gloves:

Trademark, model no., size, CE icon, testing institute identification number, pictograms, i-mark, factory icon with month/year of manufacture

	Brand label of manufacturer
2162	Article no. of the manufacturer
10	Size (example)
	Pictograms with the corresponding numbers of the relevant European PPE standards (example, detailed pictogram see previous pages).
<b>CE</b>	The CE marking confirms compliance with the requirements of European Regulation 2016/425.
0598	Four-digit number of the testing institute, which monitors the quality assurance of the manufacturer. This will be attached to the CE mark on the product.
	i mark: Reference to the manufacturer's information.
	Date of manufacture month/year: 00/0000

### B. Explanation and numbers of the standards whose requirements the gloves satisfy:

Standards retrieved from: the Official Journal of the European Union. Available from Beuth Verlag GmbH, 10787 Berlin, www.beuth.de.


#### EN 420:2003+A1:2009 - General requirements and test methods for gloves

#### EN 388:2016 - Protective gloves against mechanical risks:

Protective gloves against mechanical risks must achieve at least Level 1 for at least one of the properties (abrasion, cut, tear and puncture resistance) or at least Level A of the TDM cut resistance test according to EN ISO 13997:1999.

Abrasion resistance:	The number of cycles needed to wear through the test glove.
Cut resistance:	The number of text cycles in which the sample is cut through at constant speed.
Tear resistance:	The force needed to continue tearing the cut sample.
Puncture resistance:	The force needed to puncture the sample using a standardized test stylus.

#### EN 388:2016

 Test criteria	Rating	Article 2162
A = Abrasion resistance	0 - 4	4
B = Cut resistance (Coupe test)	0 - 5	1
C = Tear resistance	0 - 4	2
D = Puncture resistance	0 - 4	1
E = Cut resistance (TDM) according to EN ISO 13997:1999	A - F	X
F = Impact protection test according to EN 13594:2015	P	not assessed

The higher the test number, the better the test performance. X means 'not tested'. P means 'passed'.

Test	1	2	3	4	5
A = Abrasion resistance (number of abrasion cycles)	100	500	2000	8000	-
B = Cut resistance (index) Coupe test	1,2	2,5	5,0	10,0	20,0
C = Tear resistance (N)	10	25	50	75	-
D = Puncture resistance (N)	20	60	100	150	-

Test	A	B	C	D	E	F
E = Cut resistance according to EN ISO 13997:1999 (N)	2	5	10	15	22	30
Article 2162						

#### EN 13594:2015 - Impact protection :

Every area specified as providing protection against impact must be tested. The test method (dimensions of the test sample) does not permit impact testing of the finger protection. Gloves to protect against mechanical risks may be designed and manufactured in such a way that they offer specific impact damping (e.g. impact protection on the knuckles, the back of the hand, the palms). These gloves must satisfy the requirements of Level 1 according to EN 13594:2015 .

The results of the Coupe test must only be taken as indications if blunting occurs during the cut resistance test (B), while the TDM cut resistance test (E) provides reference results in regard to performance.

#### WARNING:

**The overall classification for gloves with two or more layers does not necessarily indicate the performance of the outermost layer. Gloves with mechanical resistance that achieve and demonstrate Level 1 tear resistance (C) or higher must not be worn if there is a risk of them catching when operating machines with moving parts. Tests are taken from the palm area of the glove.**

#### EN 511:2006 - Protective gloves against cold:

This Pictogram indicates that the product protects against convective and conductive cold and complies under EN 511:2006.



Test criteria	Possible performance levels	Article 2162
Convective cold (table 1)	0 - 4	1
Contact cold (table 2)	0 - 4	1
Water penetration	0 - 1	1

**Table 1 - Thermal insulation values:**

Performance level	Thermal insulation ITR in m <sup>2</sup> K/W
1	$0,10 \leq \text{ITR} < 0,15$
2	$0,15 \leq \text{ITR} < 0,22$
3	$0,22 \leq \text{ITR} < 0,30$
4	$0,30 \leq \text{ITR}$

**Table 2 - Thermal resistance values:**

Performance level	Thermal resistance ITR in m <sup>2</sup> K/W
1	$0,025 \leq R < 0,050$
2	$0,050 \leq R < 0,100$
3	$0,100 \leq R < 0,150$
4	$0,150 \leq R$

The higher the test number, the higher the test performance. The code 'X' in place of a number indicates that the glove was not designed for applications covered by this test. Gloves in Levels 2 to 4 for convective cold must achieve at least Level 2 for abrasion resistance and tear resistance according to EN 388:2016; the highest level for convective cold must otherwise be given as Level 1.

The levels and their protective effects only apply to the complete assembly for gloves that consist of several parts.

**WARNING:**

**Gloves that do not do not fulfil the criteria of Level 1 for water penetration may lose their insulating properties when exposed to damp.**

**Protective gloves against dangerous chemicals and micro-organisms:**

EN ISO 374-1:2016, Part 1:

Terminology and performance requirements for chemical risks

EN 374-2:2014, Part 2:

Determination of resistance to penetration

EN 374-4:2013, Part 4:

Determination of resistance to degradation by chemicals

EN ISO 374-5:2016, Part 5:

Terminology and performance requirements for risks by micro-organisms

EN 16523-1:2015, Part 1:

Determination of material resistance to permeation by chemicals - Part 1 Permeation by liquid chemicals under conditions of continuous contact

**Definition of terms:**

Degradation:	An adverse change in one or more properties of a material used in a protective glove due to contact with a chemical. NB: Examples of degradation include flaking, swelling, disintegration, embrittlement, discolouration, a change in appearance, hardening or softening etc.
Penetration:	Movement of a chemical through materials, seams, pinholes or other imperfections in the protective glove material at a non-molecular level.
Permeation:	Movement process of a chemical through the material of the protective glove material at a molecular level. NB: Permeation includes the following: Absorption of molecules of the chemical into the contacted (outside) surface of a material; Diffusion of the absorbed molecules in the material; Desorption of the molecules from the opposite (inside) surface of the material.

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

Article	Result article 2162
Resistance to Bacteria & Fungi	passed
Resistance to Virus	passed

**Resistance to penetration EN 374-2:2014 Acceptable quality limit (AQL):**

Performance level	Acceptable quality limit (AQL)	Inspection level	Article 2162
3	< 0,65	G1	AQL = 0,65
2	< 1,50	G1	
1	< 4,00	S4	

**Resistance to degradation EN 374-4:2013:**

Code letter	Test chemical	CAS-RN	Class	Article 2162
A	Methanol	67-56-1	Primary alcohol	swelling, 6.4%
K	Sodium hydroxide 40%	1310-73-2	Inorganic alkali	no change, -11.7%
L	Sulphuric acid 96%	7664-93-9	Inorganic acid, oxidizing	no change, 3.6%
M	Nitric acid 65%	7697-37-2	Inorganic acid, oxidizing	swelling and discoloration, 22.0%
P	Hydrogen peroxide 30%	7722-84-1	Peroxide	swelling, 5.2%
S	Hydrofluoric acid 40%	7664-39-3	Inorganic acid	not tested
T	Formaldehyde 37%	50-00-0	Aldehyde	swelling, -1.8%

**Material resistance to permeation by chemicals EN ISO 374-1:2016:**

Breakthrough time (min.)	Performance level for permeation
> 10	1
> 30	2
> 60	3
> 120	4
> 240	5
> 480	6

**Protective gloves against chemicals are classified in three types, based on their permeation performance:**

- Type A: The permeation performance must satisfy at least Level 2 for no less than six test chemicals according to the following table.
- Type B: The permeation performance must satisfy at least Level 2 for no less than three test chemicals according to the following table.
- Type C: The permeation performance must satisfy at least Level 1 for no less than one test chemical according to the following table.

**List of test chemicals:**

Code letter	Test chemical	CAS-RN	Class	Breakthrough time (min.) art. 2162	Level art. 2162
A	Methanol	67-56-1	Primary alcohol	63	3
B	Acetone	67-64-1	Ketone		
C	Acetonitril	75-05-8	Nitrile		
D	Dichloromethane	75-09-2	Chlorinated hydrocarbon		
E	Carbon sulphide	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 compounds		
I	Ethyl acetate	141-78-6	Ester		
J	n-heptane	142-82-5	Aliphatic hydrocarbons		
K	Sodium hydroxide 40%	1310-73-2	Inorganic alkali	> 480	6
L	Sulphuric acid 96%	7664-93-9	Inorganic acid, oxidizing	109	3
M	Nitric acid 65%	7697-37-2	Inorganic acid, oxidizing	105	3
N	Acetic acid 99%	64-19-7	Organic acid		
O	Ammonia water 25%	1336-21-6	Organic alkali		
P	Hydrogen peroxide 30%	7722-84-1	Peroxide	> 480	6
S	Hydrofluoric acid 40%	7664-39-3	Inorganic acid	300	5
T	Formaldehyde 37%	50-00-0	Aldehyde	> 480	6

**Marking of the glove:****Type A:**

The seven tested chemicals must be identified by their code letter, positioned below the pictogram as shown below. If chemicals not included in the list are also tested, information on the performance levels must be made available in the user instructions.

EN ISO 374-1:2016/Type A



AKLMPST

**WARNINGS:**

This information does not provide any details on the actual duration of protection at the workplace; it also does not distinguish between blends and pure chemicals. Resistance to chemicals was assessed using samples taken only from the palm and tested under laboratory conditions (apart from the glove measures 400 mm or longer, in which case the cuff is also tested); the stated resistance refers only to the tested chemicals. Resistance may differ if the chemical is present in a blend.

Users are recommended to check whether the glove is suitable for its intended application, as the conditions at the workplace may differ from those during type testing, depending on the temperature, abrasion and degradation.

Protective gloves that have already been used may provide less resistance to dangerous chemicals due to changes in their physical properties. The actual service life may be reduced significantly due to degradation, movement, stringing, abrasion and suchlike, caused by contact with chemicals. Degradation may be the most significant factor in regard to aggressive chemicals; this must be duly considered in the selection of protective gloves against chemicals.

EN 374-4:2013 Degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.

The gloves must always be checked for imperfections before use.

The manufacturer must provide decontamination instructions for reusable gloves. Gloves are for single-use only if they do not include decontamination instructions, and the following warning must be added: To be used only once.

**Protection against micro-organisms (bacteria and fungi) according to EN ISO 374-5:2016****Marking of gloves that protect against bacteria and fungi:**

EN ISO 374-5:2016

**Marking of gloves that protect against viruses, bacteria and fungi:**

The bacteriophage penetration test according to ISO 16604:2004 (method B) must be performed and passed if a protection against viruses be stated.

EN ISO 374-5:2016



VIRUS

**WARNINGS:**

Resistance to penetration was assessed under laboratory conditions and refers exclusively to the tested samples.

**C. Purpose, applications and risk assessment:**

Applicable for light general work with high risks of exposure to cold, e.g. in the craft trade, construction sector, chemical industry, pharmaceutical industry, food industry, fish industry, agricultural sector, facility management, logistics

These gloves satisfy the requirements of the quoted standards. Please note that the actual conditions of use cannot be simulated and that the decision on the glove's suitability for its intended purpose therefore lies exclusively with the user. The manufacturer is not responsible for improper use. Hence, an assessment of the residual risk should be performed before use in order to determine whether this glove is suitable for its intended purpose.

Kindly note the printed pictograms and performance levels.

**Precautionary measures during use:**

- Only use gloves with a printed chemical pictogram when handling chemicals.
- Make certain that the selected glove is resistant to the chemicals being used.
- Do not use these gloves to protect against serrated edges or blades, etc.
- If gloves for heat application are requested, make certain that they satisfy the requirements of EN 407 and that they were tested as specified therein.

- Do not use the gloves close to moving machine parts.
- Check the gloves carefully before use to make certain there are no defects or imperfections.
- Gloves meeting the requirement for resistance to puncture in accordance with EN388:2016 may not be suitable for protection against sharply pointed objects such as hypodermic needles.
- Discard damaged, worn, dirty or soiled gloves, irrespective of the substance (including on the inside), as they may lead to skin irritation and rashes. Consult a doctor or dermatologist should such cases arise.
- For further information regarding the permissible user exposure, e.g. temperature, duration please contact the manufacturer.

#### **D. Cleaning, care and disinfecting:**

##### **Care instructions:**



Do not wash and bleach the gloves. Drying in tumbler is not possible. Do not iron. Professional dry and wet cleaning is not allowed.

Both new and used gloves must be checked carefully for any damage before they are worn. Never store dirty gloves if they are intended for reuse. Users are advised to carefully remove the gloves on the right and then the left if it is not possible to remove the soiling or if doing so would present a danger. Here, use the hand wearing the glove in such a way that the other glove can be removed without coming into contact with the soiling.

#### **E. Storage and ageing:**

Keep in a cool, dry place; do not expose to direct sunlight; keep away from any ignition sources; store in the original packaging if possible. The mechanical properties of the gloves will not change for a period of up to 3 years from the manufacturing date, provided they are stored as recommended. A precise service life cannot be stated, as it depends on the type of use and on whether the user ensures that the gloves are used exclusively for their intended purpose. The manufacturing date (month/year) is stated on the gloves.

#### **F. Disposal:**

Used gloves may be contaminated with environmentally harmful or hazardous substances. Dispose of the gloves in accordance with applicable local laws.

#### **G. Material composition:**

**Carrier material: cotton jersey (brushed, laminated with foam and cotton)**

**Coating: polyester fabric with polyvinylchloride (PVC)**

#### **H. Packaging:**

This item will be delivered in a uniform cardboard box with a content of: 60 pair

The smallest sales unit is: 6 pair

#### **I. Health risks:**

There have been no reported incidents of allergies provoked by use of the gloves for their intended purpose. You should nonetheless consult a doctor or dermatologist if you experience an allergic reaction.

#### **Notified body responsible for the EU Type Examination:**

SATRA Technology Europe Ltd.

Bracetown Business Park

Clonee, Dublin D15 YN2P

Ireland

(Notified Body No.: 2777)

in accordance with EU Regulation 2016/425.

#### **Notified body that monitors the manufacturer's quality assurance based on the production process (module D, in accordance with Annex VIII of PPE regulation (EU) 2016/425):**

SGS Fimko Oy

P.O. Box 30 (Särkiniementie 3)

00211 Helsinki

Finland

Notified Body number: 0598

#### **Manufacturer's name and address:**

BIG Arbeitsschutz GmbH, Königsberger Str. 6, 21244 Buchholz/Nordheide, Germany

**For the full Declaration of Conformity and additional technical information, please visit:**

**[www.big-arbeitsschutz.de](http://www.big-arbeitsschutz.de)**

