

GLOVE SYMBOLS & TERMINOLOGY

Santé is committed to ensuring the highest available regulatory standards. Gloves sold worldwide are certified per the European Union's Personal Protective Equipment Directive & relevant EN standards, are CE marked, TGA & FDA compliant.



EN21420 - General Requirements



This symbol indicates that the user should consult the 'instructions for use'.

EN388 - Mechanical Protection



Performance Levels	1	2	3	4	5
A. Abrasion resistance (cycles)	100	500	2000	8000	-
B. Blade cut resistance (index)	1.2	2.5	5.0	10.0	20.0
C. Tear resistance (newton)	10	25	50	75	-
D. Puncture resistance (newton)	20	60	100	150	-

EN374 - Chemical Protection and/or micro-organisms

Micro-organisms



EN level ≥ 2

Performance Levels	1	2	3
AQL (Acceptable Quality Level) for liquid protection. A high index number is poor & a low index number is good.	4.0	1.5	0.65

Chemical Protection



Breakthrough time > 30 minutes for at least three chemicals from this list (XYZ represent the code letters for three of these chemicals for which the glove obtained > 30 minutes breakthrough time.

A. Methanol
B. Acetone
C. Acetonitrile
D. Dichloromethane
E. Carbon disulphide
F. Toluene
G. Diethylamine
H. Tetrahydrofurane
I. Ethyl acetate
J. n-Heptane
K. Sodium hydroxide 40%
L. Sulphuric acid 96%

Performance Levels	0	1	2	3	4	5	6
Minutes	<10	10	30	60	120	240	>480

Chemical resistance against chemicals of choice (AQL <4)



This symbol can be used for gloves that don't need the above requirement & have an AQL of two or lower.

EN421 - Radioactive contamination + ionizing radiation



Gloves protecting from direct contact with radio-active substances.



Gloves protecting from direct contact with radiations (X-ray, alpha-, beta-, gamma-, or neutron radiations).

EN1186 - Food Safety



This regulation must be met for all gloves & equipment to be able to safely come into contact with food & limit the release of trace amounts of plastics.

Overall migration limit (OML): Max. amount of non-volatile substances that can be released into food.

Specific migration limit (SML): Max. amount of metal that can be released into food.

EN455 Parts 1-4: 2009 to 2009 - Medical Gloves for single use

EN455-1 Covers requirements and testing of gloves for freedom from holes.

EN455-2 Covers requirements and tests for physical properties such as dimensions (length & width) and force at break both before and after heat ageing.

EN455-3 Covers requirements and tests for biological evaluation, includes test procedures for measuring endotoxin contamination of sterile gloves, powder residue for powder free gloves and leachable proteins in natural rubber latex gloves.

EN455-4 Covers requirements and testing for shelf life determination, by using real time studies or a suitably validated alternative.

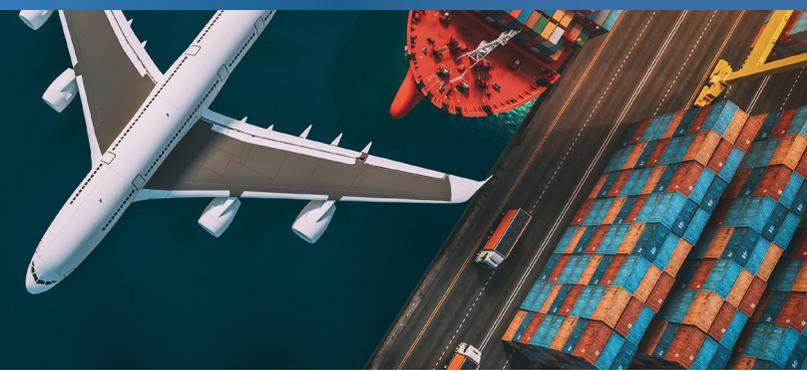
ASTM D6978-05(2019) - Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs

Testing in accordance with this standard requires the use of at least nine chemotherapy drugs – 7 compulsory drugs and a minimum of 2 additional drugs from a choice of 17. The full list of 32 drugs includes the four common methods in which chemotherapy drugs affect cancer cells.

These are by:

- damaging the DNA of the cancer cells,
- by replacing some sections of the cancer cell DNA,
- by damaging the enzymes within the cancer cells and
- by preventing the cancer cells from duplicating.

General information on the Personal Protective Equipment Regulation.



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

BS EN ISO 374-1:2016	Terminology and performance requirements for chemical risks.
BS EN 374-2:2014	Determination of resistance to penetration.
BS EN 374-4:2013	Determination of resistance to degradation by chemicals.
BS EN ISO 374-5:2016	Terminology and performance requirements for micro-organisms risks. If gloves provide protection against viruses, in addition to fungi and bacteria, further testing to ISO 16604 Clothing for protection against contact with blood and body fluids is required.
BS EN 16523-1:2015	Determination of material resistance to permeation by chemicals. Permeation by liquid chemical under conditions of continuous contact.

BS EN 388:2016+A1:2018 - Protective gloves against mechanical risks.

EN 388, 6.1	Abrasion resistance, scale index 0-4.
EN 388, 6.2	Blade cut resistance, using coupe test method (circular rotating blade under fixed 5N force), scale 0-5.
EN 388, 6.3	Since 2016 update to the standard, if the coupe blade test is blunted during testing, the glove must also undergo cut testing under EN ISO 13997:1997 method (straight blade, fluctuating between 2-30 N force), scale index A-F.
EN 388, 6.4	Tear resistance, scale index 0-4.
EN 388, 6.5	Puncture resistance, scale index 0-4.

Impact test, marking P if level 1 requirements of EN 13594:2015 achieved.
More typically used for work gloves, specifically those protecting against mechanical risks. EN388 rating achieved must be printed/displayed on the glove itself using the EN388 pictogram.
Example rating would look like the following:

EN 388, 6.6



For gloves that do not meet the minimum requirements of level 1 for each element, a 0 is typically displayed. The EN388 rating for a nitrile examination glove would most likely be 0000X.

BS EN ISO 21420:2019 Protective gloves – general requirements and test method.

This replaces EN 420:2003+A1:2009

This standard is the general requirements standard for protective gloves and has been adopted by ISO to become a worldwide standard.

Some of the key requirements listed under this standard are;

- Glove design and construction
- Chemical innocuousness
- Comfort and efficiency (sizing and dexterity)
- Information supplied by the manufacturer.

BS EN 1186 - Materials and articles in contact with foodstuffs. Plastics.

BS EN 1186-1:2002	Guide to the selection of conditions and test methods for overall migration.
BS EN 1186-2:2002	Test methods for overall migration into olive oil by total immersion.
BS EN 1186-3:2002	Test methods for overall migration into aqueous food simulants by total immersion.
BS EN 1186-4:2002	Test methods for overall migration into olive oil by cell.
BS EN 1186-5:2002	Test methods for overall migration into aqueous food simulants by cell.
BS EN 1186-6:2002	Test methods for overall migration into olive oil using a pouch.
BS EN 1186-7:2002	Test methods for overall migration into aqueous food simulants using a pouch.
BS EN 1186-8:2002	Test methods for overall migration into olive oil by article filling.
BS EN 1186-9:2002	Test methods for overall migration into aqueous food simulants by article filling.
BS EN 1186-10:2002	Test methods for overall migration into olive oil (modified method for use in cases where incomplete extraction of olive oil occurs).
BS EN 1186-11:2002	Test methods for overall migration into mixtures of C-labelled synthetic triglycerides.
BS EN 1186-12:2002	Test methods for overall migration at low temperatures.
BS EN 1186-13:2002	Test methods for overall migration at high temperatures.
BS EN 1186-14:2002	Test methods for 'substitute tests' for overall migration from plastics intended to come into contact with fatty foodstuffs using test media iso-octane and 95% ethanol.
BS EN 1186-15:2002	Alternative test methods to migration into fatty food simulants by rapid extraction into iso-octane and/or 95 % ethanol.



EN Guide explanation of three risk categories according to European legislation & industry terminology.

Complying with the PPE directive: 89/686/EEC

The directive specifies two classes of gloves meeting two levels of risk: 'minimal' and 'mortal' or 'irreversible' risk. A risk which falls between these two levels may be described as 'intermediate'. To comply with the 89/686/EEC Directive, you must establish the level of risk and select gloves of the appropriate class. A system of marking has been developed to help you in that selection.

Risk Category I: Gloves of simple design.

For minimal risk only.

For gloves of simple design offering protection from low level risks, e.g. janitorial gloves, manufacturers are permitted to test and certify gloves internally (i.e. there is no requirement for testing and certification by an independent body).

Risk Category II: Gloves of intermediate design.

For intermediate risk.

Gloves designed to protect against intermediate risk, e.g. general handling gloves requiring good cut, puncture and abrasion performance, must be subjected to independent testing and certification by a notified body. Only these approved bodies may issue a CE mark, without which the gloves may not be sold. Each notified body has its own identification number. The name and address of the notified body that certifies the product has to appear on the instructions for use that will accompany the gloves. Gloves of this category are CE marked as follows:



Risk Category III: Gloves of complex design.

For irreversible or mortal risk.

Gloves designed to protect against the highest levels of risk e.g. chemicals, must also be tested and certified by a notified body. In addition, the quality assurance system used by the manufacturer to guarantee homogeneity of production or the quality consistency testing of the final product must be independently checked. The body carrying out this evaluation will be identified by a number which must appear alongside the CE mark (in this case, 0493). Gloves of complex design are CE marked as follows:



Medical Grade	Medical grade gloves are approved for use in hospital, nursing home, or laboratory locations and are generally used for non-surgical procedures such as medical examinations.
Food Grade	Food grade gloves are approved for use for food applications such as preparing food in restaurants or for use in food processing industries.
Allergens	This refers to latex protein present in gloves that could potentially cause allergies.
Tensile Strength	Tensile strength refers to how stretched the gloves can become without ripping or tearing.
Powdered	Powdered gloves have corn starch added to help absorb perspiration. They are generally easier to don than powder-free gloves but their powdered design has been known to cause some allergies.
Powder-Free	Powder-free gloves go through a process known as chlorination. They are a good option for those that have allergies or sensitivities to powdered gloves.
Donning	To put a glove on.
Doffing	To remove a glove.
Beaded Cuff	Refers to a rolled cuff style, which adds strength and reduces liquid roll off.
Chlorination	Gloves are treated with a chlorine solution, rinsed, and dried to get rid of the powdered residue, and latex proteins.
Flock Lined	A flocked lining refers to a lining on the inside of a rubber or household glove that makes them more comfortable to wear.
Textured	The finish on the glove designed to allow for a firmer grip to prevent slipping when handling wet objects. This can be just on the finger 'finger textured' or the whole glove 'fully textured'.
Accelerator	Chemicals added to the glove during manufacture to add strength and elasticity and increase the shelf life of disposable gloves. They have been known to cause allergies in some instances, and there are Accelerator free options.
AQL	AQL stands for "Acceptable Quality Level" and refers to an internationally used quality standard for measuring the % of pinhole leaks in disposable gloves. The test process involves checking batches of gloves during manufacturing to see how watertight they are. 1.5 AQL is the standard in the medical world. Gloves with an AQL of 4.0 are not suitable for medical use, they are for industrial and domestic use e.g. cleaning, garages, engineering, dirty factory jobs etc.
Breakthrough Time	The number of minutes it takes for a gloved hand from coming into contact with a chemical until the chemical has broken through the glove and is in contact with your skin.