Gloves Education

Latex and Nitrile gloves industry

"The right glove for the right application, only when it is necessary, to meet the needs of compliance, comfort and protection".

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LABORATORY AND CLEANROOM GLOVE AQL

“What does this mean in terms of hand protection?”

What is the AQL of your nitrile or latex glove (Acceptable Quality Level)?

Single-use protective gloves or disposable gloves are commonly used in laboratory and cleanroom environments, but how certain are you that your hands are well protected? There is a simple way to find out how well you are protected: look for the AQL of your nitrile, neoprene or latex gloves.**The acronym AQL frequently appears on the laboratory glove dispenser or on cleanroom glove bags followed by numbers such as 4.0, 1.5, 0.65 or even 0.25** and alongside these figures there will often be a performance level. Usually, they refer to the results of a water or air penetration test that is undertaken to detect microporous holes. This test is carried out according to the methodology detailed in ISO 374-2:2019 and is important for giving users a certain level of protection against pinholes, tears, and other weak points.

If your nitrile gloves or latex gloves comply with the standards for protection against chemical and biological hazards (as defined by ISO 374-1:2016+A1), then there is an obligation for the disposable gloves manufacturer to indicate the level of AQL on the packaging.

AQL is determined through a sampling procedure: as not all nitrile or latex gloves in a batch can be individually checked, a certain number of disposable gloves is taken from each production lot for testing. Thus, depending on the level of AQL, the maximum percentage of defective products considered as acceptable in a manufacturing batch will be defined. Samples are tested in accordance with ISO 374-2:2019 (as part of the Personal Protective Equipment (PPE) Regulation (EU) 2016/425) or EN 455-1:2000 (as part of the Medical Devices Regulation (EU) 2017/745). The water penetration resistance test is one of the most used procedures for determining the acceptable level of quality for microporous holes. Based on the results of these leak tests, an assessment of the quality of the total production can be concluded. The assumption that through random sampling, a level of statistical probability will be achieved for the entire batch is known as confidence interval. The sampling procedure must therefore strictly comply with the sampling plan, which means that the number of samples will be different depending on the size of the lot and the level of AQL sought.

What does the AQL level mean in terms of protection?

If we accept that the glove’s barrier performance of a nitrile glove or latex glove is crucial for working in a laboratory and that the best way to measure it is to perform tests for pinholes, then AQL is extremely important. **The lower the AQL, the higher the level of protection**. Thus, by choosing a single-use glove manufactured to an AQL of 0.25, the level of protection is likely to be better than a glove whose AQL is 0.65, 1.5 or 4.0. **It is therefore important to know the AQL level of your gloves to select those which offer the highest level of protection for you and your colleagues.**

To understand better what AQL means, it is necessary to understand how it is determined:

Step 1 – Selection of the desired level of AQL and the inspection level

Table A.1 of Annex A of ISO 374-2:2019 outlines the range of AQL (AQL 4.0, 1.5, 0.65 or lower depending on the acceptable product defects) and the required inspection levels. Thus, we can see that for an AQL of below 0.65, it will be necessary to comply with the requirements of a G1 inspection level.

Table A.1: Annex A (ISO 374-2:2019) on inspection levels and acceptable quality levels in a Quality Assurance procedure used for the manufacture of disposable gloves

Performance Level	Acceptable Quality Level (AQL or NQA)	Level of inspection
Level 3	<0.65	G1
Level 2	<1.5	G1
Level 1	<4.0	S4

Step 2 – Determination of sampling

Once the AQL requirement has been determined and the level of inspection known, the number of samples to be tested per batch can be established. ISO 2859-1:1999 is the most frequently used standard to determine the number of samples to be tested based on batch size and level of inspection. This standard is particularly suitable for the manufacture of disposable gloves made of nitrile, neoprene or latex, where the volumes produced are relatively high. First, it is necessary to consider the size of the lot (for disposable gloves, this is the number of gloves produced in a batch). The batch size and the level of inspection selected ("Special Inspection Levels" (S) and/or "General Inspection Levels" (G)) will determine the number of samples to be inspected.

The table below (Table 2) establishes the sample size. Each inspection level corresponds to a code letter (from A to R). For a batch for example, between 150,001 and 500,000 disposable gloves (which is the approximate volume of a typical batch of disposable gloves) and for a required AQL of less than 0.65, the inspection level, according to the requirements of ISO 374-2:2019, will therefore be G1. The sample size can then be decided by referring to the letter "M".

Table 2 – Letter coding according to the glove batch size *(according to ISO 2859-1:1999)*

Glove batch size	Special Inspection Levels (S1 to S4)				General Inspection Levels (G1 to G3)		
	S1	S2	S3	S4	G1	G2	G3
2 to 8	A	A	A	A	A	A	B
9 to 15	A	A	A	A	A	B	C
16 to 25	A	A	B	B	B	C	D
26 to 50	A	B	B	C	C	D	E
51 to 90	B	B	C	C	C	E	F
91 to 150	B	B	C	D	D	F	G
151 to 280	B	C	D	E	E	G	H
281 to 500	B	C	D	E	F	H	J
501 to 1200	C	C	E	F	G	J	K
1201 to 3200	C	D	E	G	H	K	L
3201 to 10 000	C	D	F	G	J	L	M
10 001 to 35 000	C	D	F	H	K	M	N
35 001 to 150 000	D	E	G	J	L	N	P
150 001 to 500 000	D	E	G	J	M	P	Q
500 001 and +	D	E	H	K	N	Q	R

Step 3 – Performing the test on the samples

We can see that selection of the batch size and inspection level leads us to the letter code, which in this case is "M". From the table below (Table 2-A), the letter code "M" informs us that the number of samples to be taken is 315. If the selected AQL level is <0.65 we can read in the corresponding "Normal Inspection" column, the numbers 5 and 6. This means that the batch is acceptable up to 5 defective gloves and will be rejected if there are 6 or more. In summary, for a batch of 400,000 nitrile or latex gloves, if we operate with a G1 level inspection level with an expected AQL <0.65, then we will have to test 315 disposable gloves. If there are no more than 5 defective gloves, the lot will be accepted. If there are 6 or more defective gloves, the lot will be rejected and cannot be sold.

Table 2-A — Single sampling plans for normal inspection (Master table)

Tightened, normal and reduced inspection levels

It should be noted that ISO 2859-1:1999 refers to "Tightened, Normal and Reduced" inspection levels on the assumption that if several batches have been accepted successively, the increased level of confidence in the system causes the disposable glove manufacturer to make fewer mistakes.

If, for example, 5 successive batches are "good" then the inspection level can change to the so-called "Reduced" level. If we take our example of a batch of 400,000 laboratory gloves or single-use cleanroom gloves with an AQL <0.65 and an inspection level G1, we will have, according to the table below "Table 2-C" to evaluate 125 gloves instead of 315. Conversely, if we successively reject 2 lots, we will then move to a "High" inspection level and in this case, according to the table below "Table 2-B", the sample size will remain the same (315) but the criteria for acceptance or rejection of the batch will be more severe (3 and 4 instead of 5 and 6).

Table 2-B — Single sampling plans for tightened inspection (Master table)

Sample size code letter	Sample size	Acceptance quality limit, AQL, in percent nonconforming items and nonconformities per 100 items (tightened inspection)																													
		0,010		0,015		0,025		0,040		0,065		0,10		0,15		0,25		0,40		0,65		1,0		1,5		2,5		4,0		6,5		10	
		Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re
A	2																											⇩		0	1
B	3																											0	1		
C	5																									0	1			1	2
D	8																									0	1			1	2
E	13																							0	1			1	2	2	3
F	20																					0	1			1	2	2	3	3	4
G	32																			0	1			1	2	2	3	3	4	5	6
H	50																	0	1			1	2	2	3	3	4	5	6	8	9
J	80															0	1			1	2	2	3	3	4	5	6	8	9	12	13
K	125													0	1			1	2	2	3	3	4	5	6	8	9	12	13	18	19
L	200											0	1			1	2	2	3	3	4	5	6	8	9	12	13	18	19		
M	315									0	1			1	2	2	3	3	4	5	6	8	9	12	13	18	19				
N	500							0	1			1	2	2	3	3	4	5	6	8	9	12	13	18	19						
P	800					0	1					1	2	2	3	3	4	5	6	8	9	12	13	18	19						
Q	1 250			0	1					1	2	2	3	3	4	5	6	8	9	12	13	18	19								
R	2 000	0	1			⇩		1	2	2	3	3	4	5	6	8	9	12	13	18	19	⇩									
S	3 150					1	2																								

Sample size code letter	Sample size	10		15		25		40		65		100		150		250		400		650		1 000	
		Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re
A	2	⇩				⇩		1	2	2	3	3	4	5	6	8	9	12	13	18	19	27	28
B	3	0	1	⇩		1	2	2	3	3	4	5	6	8	9	12	13	18	19	27	28	41	42
C	5			1	2	2	3	3	4	5	6	8	9	12	13	18	19	27	28	41	42	⇧	
D	8	1	2	2	3	3	4	5	6	8	9	12	13	18	19	27	28	41	42	⇧			
E	13	2	3	3	4	5	6	8	9	12	13	18	19	27	28	41	42	⇧					
F	20	3	4	5	6	8	9	12	13	18	19	⇧											
G	32	5	6	8	9	12	13	18	19	⇧													
H	50	8	9	12	13	18	19	⇧															
J	80	12	13	18	19	⇧																	
K	125	18	19	⇧																			
L	200	⇧																					
M	315																						
N	500																						
P	800																						
Q	1 250																						
R	2 000																						
S	3 150																						

⇩ = Use the first sampling plan below the arrow. If sample size equals, or exceeds, lot size, carry out 100 % inspection.

⇧ = Use the first sampling plan above the arrow.

Ac = Acceptance number

Re = Rejection number

Table 2-C — Single sampling plans for reduced inspection (Master table)

⇩ = Use the first sampling plan below the arrow. If sample size equals, or exceeds, lot size, carry out 100 % inspection.

⇧ = Use the first sampling plan above the arrow.

Ac = Acceptance number

Re = Rejection number

Is there a difference in the sampling procedure between laboratory gloves or cleanroom gloves that comply with Regulation (EU) 2017/745 on Medical Devices (MD) and disposable gloves that comply with Regulation (EU) 2016/425 on Personal Protective Equipment (PPE)?

Single-use gloves can be certified either as MD or PPE or can have dual registration. The test procedures for the detection of microporous holes are described respectively in EN 455-2:2015 for MD gloves and in ISO 374-2:2019 for PPE gloves. Although the sampling of the 2 types of gloves refers to ISO 2859-1:1999, a "general inspection level" of 1 (G1) is required and the AQL must be at least 1.5, EN 455-1:2000 requires a sample size corresponding to the letter code "L". If we take our example, for a batch of 400,000 gloves, the sample size corresponding to the letter "L" will be 200 with the number of products accepted/rejected respectively of 7 and 8 (instead of 10 and 11 for the letter M). This means that sampling procedures in some circumstances may be more stringent for disposable "Medical Device" gloves than for disposable "PPE" gloves.

Conclusion

As many nitrile gloves or disposable latex gloves used in laboratories or cleanroom workplaces are tested against ISO 374-2:2019 as part of their registration process as Category III PPE, the identification of AQL should be relatively easy. We have also seen that AQL is a statistical method for determining the quality of a glove (as defined in ISO 2859-1:1999) and that the detection of pinholes is of paramount importance for assessing the barrier properties of a nitrile glove or latex glove.

- ALSO, REMEMBER THAT: THE LOWER THE AQL (0.25, 0.65 rather than 1.5 or 4.0),THE BETTER YOU WILL BE PROTECTED!
- THE THICKER AND LONGER THE GLOVE, THE BETTER YOU WILL BE PROTECTED!
- THE BEST CHEMICAL PROTECTION IN THE LABORATORY!

In response to laboratory workers demand for a glove offering a higher level of chemical protection in the laboratory but without compromising dexterity and comfort.

Remember: on paper all gloves may comply with the same Standards. But, as you'll have noticed they may not offer the same level of performance!

UNDERSTANDING PERMEATION TEST FOR CHEMICAL RESISTANT GLOVES

For better protection of laboratory workers, the highest level of chemical protection should be provided. When we talk about disposable chemical resistant gloves, we are referring to gloves that are designed to protect against chemical hazards. As such, they will have been subjected to different tests: permeation, penetration, and degradation. In this article, we will focus on the permeation test method used for gloves.

WHAT IS THE CONTEXT TO THE EU CHEMICAL PERMEATION STANDARD?

- The standard EN 16523-1:2015+A1:2018 relates to the permeation test method used with Personal Protective Equipment (PPE) gloves.
- It is linked to the ISO 374-1:2016+A1:2018 standard. This standard describes the framework, the performance levels and markings of gloves resistant to chemicals.

WHAT DOES PERMEATION MEAN?

"Permeation" is the process by which a chemical moves through a material at the molecular level.

A priority for laboratory workers seeking the best safety conditions at work is to wear gloves which offer the best chemical permeation test results with the relation to the chemicals being used.

WHAT IS GLOVE PERMEATION TEST?

The "permeation" test measures the barrier effectiveness of latex and nitrile gloves to exposure from a liquid chemical according to the EN 16523-1:2015+A1:2018 standard.

The permeation test provides information on the breakthrough time.

It is a useful method for evaluating the barrier effectiveness of a glove when immersed in a liquid chemical under conditions of continuous contact and at room temperature (23°C +/-1).

It measures how quickly a liquid chemical moves through the glove material.

The normalised permeation rate is defined as 1µg/min/cm² and the maximum duration for the test is 480 minutes. Test results are reported based upon the Normalized Breakthrough Time (NBT) achieved.

WHICH CHEMICALS ARE TESTED?

A list of 18 chemicals are specified in ISO 374-1:2016+A1:2018 (see below) and represent the requisite test chemicals.

CODE LETTER	CHEMICAL	CAS NUMBER	CODE LETTER	CHEMICAL	CAS NUMBER
A	Methanol	67-56-1	J	n-heptane	142-82-5
B	Acetone	67-64-1	K	Sodium hydroxide 40%	1310-73-2
C	Acetonitrile	75-05-8	L	Suphuric acid 96%	7664-93-9
D	Dichloromethane	75-09-2	M	Nitric acid 65 %	7697-37-2
E	Carbon disulphide	75-15-0	N	Acetic acid 99 %	64-19-7
F	Toluene	108-88-3	O	Ammonium hydroxide 25%	1336-21-6
G	Diethylamine	109-89-7	P	Hydrogen proxide 30%	7722-84-1
H	Tetrahydrofuran	109-99-9	S	Hydrofluoric acid 40%	7664-39-3
I	Ethyl acetate	141-78-6	T	Formaldehyde 37%	50-00-0

we strongly believe that types (A,B or C) or performance levels (from 0 to 6) are not enough information for choosing the right glove for your protection against chemicals.

That is why we will always indicate in our documentation the exact breakthrough time for the chemicals tested. Always bear in mind the thickness will have an important impact on the breakthrough time (the thicker the better even if gloves are type A!). Furthermore, we provide an extended Chemical resistance guide on our website where you can search and sort information by chemical, by case number or by glove.

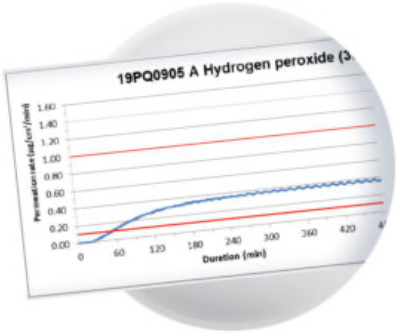
WHAT ARE THE KEY STEPS IN THE GLOVES PERMEATION TEST?

STEP 1- PERMEATION TEST: SAMPLING PHASE

Three test specimens are typically taken from the palm area. If the glove is longer than or equal to 400 mm and if it is claimed that cuff offers protection against the chemical risks, then three additional test specimens shall be taken from the cuff area.

STEP 2 – PERMEATION TEST: TESTING PHASE

The permeation cell consists of two compartments, separated by the test specimen. The specimen's outer surface is in contact with the challenge chemical, whereas the specimen's inner surface is in contact with a collecting medium.



STEP 3 – PERMEATION TEST: RESULTS PHASE

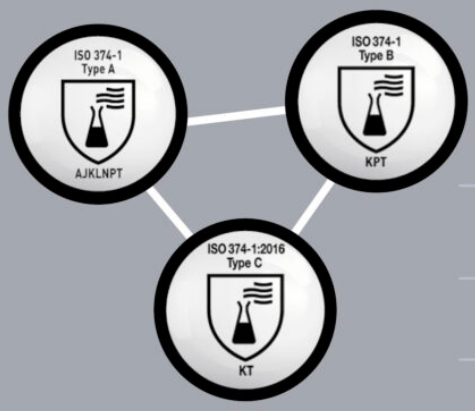
The breakthrough time is deemed to have occurred when the permeation rate of the challenge chemical reaches the normalized permeation rate (1µg/min/cm²). The result is then reported in minutes. The results of the three tests must be within a range of + or – 20% of the average result for the three samples evaluated. If the three results are not within the defined range, the test must be repeated. In the event of non-conformance, then the results shall not be disclosed. The lowest result of the three samples tested must be declared.

There are six permeation performance levels. Level 6, which is the highest, shows a breakthrough time greater than 480 minutes.

MEASURED BREAKTHROUGH TIME (min)	**PERFORMANCE LEVEL**
10-30 min	Level 1
30-60 min	Level 2
60-120 min	Level 3
120-240 min	Level 4
240-480 min	Level 5
> 480	Level 6

HOW ARE CHEMICAL PROTECTIVE GLOVES CLASSIFIED?

Gloves are classified as type A, B or C depending on their performance level when tested against a number of test chemicals (as outlined in ISO 374-1:2016+A1:2018).



CLASSIFICATION	MINIMUM PERFORMANCE LEVEL REQUIRED	MINIMUM NUMBER OF CHEMICALS FROM THE 18 LISTED
Type A	Level 2 (min 30 minutes breakthrough)	6
Type B	Level 2 (min 30 minutes breakthrough)	3
Type C	Level 1 (min 10 minutes breakthrough)	1

WHAT ARE THE LIMITS TO THE DISPOSABLE GLOVE PERMEATION TEST?

"HIGHER TEMPERATURE CAN MAKE THE BREAKTHROUGH TIME SHORTER"

It should be noted that physical stress is not considered when testing the glove and that a higher ambient temperature or higher chemical concentrations can make the breakthrough time shorter.

Additionally, as body temperature is around 37°C, the temperature experienced by the disposable glove will rise during its use. This will impact on the effectiveness of the glove barrier. It is evident that temperature has a significant influence on the result. Therefore, it may be prudent to give laboratory workers a safety margin in terms of deciding when to discard gloves and replace them with new ones!

The information given is for guidance only and may not reflect the user's application. A risk assessment should always be made by the user to assess the suitability of gloves for a specific application. Note that the test method according to ASTM F739 is similar but the rate is defined as 0.1µg/min/cm². Therefore, with a lower rate, gloves tested against this US Standard with the same chemical/same % are likely to feature a poorer result. Last but not the least, the classification considers only 18 chemicals.

Most of the time the chemicals used in the laboratory are not part of this list, so whether a glove is Type A, B or C may have limited application for these users.

REGULATIONS AND STANDARDS RELATING TO LABORATORY GLOVES AND CLEANROOM GLOVES

Complex Design covers the highest level of risk, otherwise defined as irreversible and mortal risk. Disposable gloves in this category are typically those gloves that provide protection against chemical and microorganisms. For these gloves the following normative references may apply: ISO 21420:2020 (general requirements for gloves), ISO 374-1:2016+A1:2018 (terminology and performance requirements for chemical risks) and ISO 374-5:2016 (terminology and performance requirements for micro-organisms risks).

Crucially complex design brings the need for regular auditing by an external organization body, called a Notified Body. The presence of the Notified Body is clearly evident, as under the CE mark will appear four digits (e.g. 0598 = SGS, 0493=Centexbel, 0123=TÜV etc). The Notified Body validates the quality assurance system used by the manufacturer.

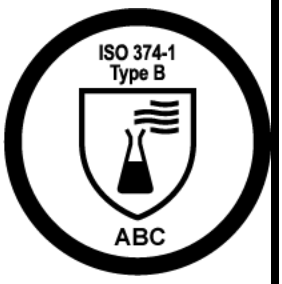
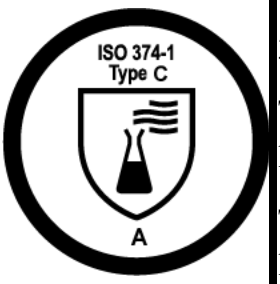
In addition, disposable gloves that have been registered as Complex Design will typically display two or three pictograms identifying the relevant standards to which they have been tested.

REFERENCE	SCOPE	PICTOGRAM
Regulation (EU) 2016/425	General requirements for the design and manufacture of Personal Protective Equipment (PPE). User Information	PPE Cat. I & II CE PPE Cat.III CE XXXX
Regulation (EU) 2017/745	Medical devices Directive.	CE
ISO 21420:2020	Protective gloves – General requirements and test methods for glove design, construction, resistance of glove materials to water penetration, innocuousness, comfort and efficiency, marking and information supplied by the manufacturer applicable to all protective gloves.	**N/A**

CHEMICAL RISK

REFERENCE	SCOPE
ISO 374-1:2016+A1:2018	Protective gloves against dangerous chemicals and micro-organisms – Part 1: Terminology and performance requirements for chemical risks.
EN 16523-1:2015+A1:2018	Determination of material resistance to permeation by chemicals – Part 1: Permeation by liquid chemical under conditions of continuous contact.
ISO 374-2:2019	Protective gloves against dangerous chemicals and micro-organisms – Part 2: Determination of resistance to penetration.
ISO 374-4:2019	Protective gloves against dangerous chemicals and micro-organisms – Part 4: Determination of resistance to degradation by chemicals.

Gloves are classified as Type A, B or C depending on their performance level when tested against a number of chemicals and degradation expressed in terms of mean average (% change in puncture resistance before and after chemical exposure).

TYPE A	TYPE B	TYPE C	PERFORMANCE
			TYPE A: 6 out 18 chemicals with at least 30 minutes breakthrough (Level 2). TYPE B: 3 out of 18 chemicals with at least 30 minutes breakthrough (Level 2). TYPE C: 1 out of 18 chemicals with at least 10 minutes breakthrough(Level 1).

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

BIOLOGICAL RISK

REFERENCE	SCOPE
ISO 374-5:2016	Protective gloves against dangerous chemicals and micro-organisms – Part 5: Terminology and performance requirements for micro-organisms risks.
ISO 374-2:2019	Protective gloves against dangerous chemicals and micro-organisms – Part 2: Determination of resistance to penetration.
ISO 16604:2004 Procedure B	Clothing for protection against contact with blood and body fluids – Determination of resistance of protective clothing materials to penetration by blood-borne pathogens – Test method using Phi-X174 bacteriophage.

ISO 374-2 :2019 remains the basic test for assessing resistance to penetration by micro-organisms. Here performance is measured on the basis of AQL (AQL<4 or Level 1 to AQL <0.65 or Level 3, with Level 3 being the highest performance level). For protective gloves against bacteria and fungi, the biohazard pictogram is applied.

For protection against bacteria, fungi, and virus, the biohazard pictogram is accompanied with the term "VIRUS "underneath. To fulfil this requirement, the glove must be tested according to ISO 374-2:2019 for bacteria and fungi and also tested according to ISO 16604: 2004 (Method B) using the bacteriophage penetration test.

MICRO-ORGANISMS RESISTANT	VIRUS RESISTANT
	
Level 1	AQL<4
Level 2	AQL<1.5
Level 3	AQL<0.65

MECHANICAL RISK

REFERENCE	SCOPE	PICTOGRAM
EN 388:2016+A1:2018	Protective gloves against mechanical risks. This standard covers mechanical risks such as abrasion, blade cut, tear, puncture and if applicable impact. A pictogram identifying a glove offering protection against mechanical risks will have underneath up to four numbers and where appropriate up to two letters. These signs indicate the performance of the glove.	

RADIOACTIVE CONTAMINATION RISK

REFERENCE	SCOPE
EN 421:2010	Protective gloves against ionizing radiation and radioactive contamination.

MEDICAL USE

REFERENCE	SCOPE
EN 455-1:2020	Medical gloves for single use – Part1: Requirement and testing for freedom from holes.
EN 455-2:2015	Medical gloves for single use – Part 2: Requirement and testing for physical properties.
EN 455-3:2015	Medical gloves for single use – Part 3: Requirement and testing for biological evaluation.
EN 455-4:2009	Medical gloves for single use – Part 4: Requirement and testing for shelf-life determination.

OTHER REGULATIONS AND STANDARDS

REFERENCE	SCOPE
ANSI/AAMI/EN ISO 1137-2:2015	Gamma Sterilization Dose Auditing
ASTM D257-07	Standard Test Methods for DC Resistance or Conductance of Insulating Materials
ASTM D257-36	Standard Test Methods for DC Resistance or Conductance of Insulating Materials

REFERENCE	SCOPE
ASTM D3578-05	Standard Specification for Rubber Examination Gloves
ASTM D3767-03 (2020)	Standard Practice for Rubber—Measurement of Dimensions
ASTM D412-06ae2	Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension
ASTM D412-06ae2	Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension
ASTM D5712-15 (2020)	Standard Test Method for Analysis of Aqueous Extractable Protein in Natural Rubber and Its Products Using the Modified Lowry Method
ASTM D6124-06	Standard Test Method for Residual Powder on Medical Gloves
ASTM D6319-10	Standard Specification for Nitrile Examination Gloves for Medical Application
ASTM D6978-05 (2019)	Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
ASTM F1671-97b	Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System
ASTM F720-81	Standard Practice for Testing Guinea Pigs for Contact Allergens: Guinea Pig Maximization Test
ASTM D573-04 (2019)	Standard Test Method for Rubber—Deterioration in an Air Oven
Directive 72/2002/EC	relating to plastic materials and articles intended to come into contact with foodstuffs
EC 1935/2004	Directive on materials and articles intended to come into contact with food
EN 1149-1/2/3 & 5	Protective clothing – Electrostatic properties
FDA 21CFR177.2600	FDA – Food for Human Consumption – Indirect Food Additives: Polymers – Rubber article intended for repeated use
IEST-RP-C005.4 (2013)	Gloves and Finger Cots Used in Cleanrooms and Other Controlled Environments
ISO 13485:2016	Medical devices – Quality management systems — Requirements for regulatory purposes
ISO 21171:2006	Medical gloves – Determination of removable surface powder
ISO 9001:2015	Quality management systems — Requirements
ISO 14001:2015	Environmental management systems