SHIELD Scientific
compliance comfort protection

LABORATORY GLOVES

WWW.SHIELDSCIENTIFIC.COM

IT'S IN THE NAME

A TOP QUALITY SERVICE

SHIELD Scientific is a European company. The headquarters are strategically based in the Netherlands. Our international logistics hub, located in Malaysia, has storage space for up to 1700 pallets (60 000 cases), whilst logistics management is tightly controlled. Our production management system is certified according to ISO 9001:2015 and ISO 13485:2016. Distribution is provided by a network of Master Distributors. At SHIELD Scientific, everyone is focused on the needs of the customer, with a view to developing long-term partnerships where the emphasis is on mutual gain.

COMPLIANCE

Following the introduction of Regulation (EU) 2016/425, SHIELD Scientific remains at the forefront offering laboratory gloves CE marked PPE category III (Complex Design) which meet or exceed European and International Standards.

DISTRIBUTOR RESOURCES

Enjoy faster response times and benefit from secure access to all the information you need.

COMFORT

Comfort is very often at the top of the user's criteria for selection of gloves. At SHIELD Scientific we continue to develop new technologies which improve users' well-being without compromising skin care and protection.

POSTER MAKER

Select your glove(s), your chemical(s), add your logo and your warning notifications: create your own poster!

PROTECTION

When selecting a glove, its protective properties are often lost in the jungle of features offered to users by the manufacturers. At SHIELD Scientific we believe that THE THICKER AND LONGER THE GLOVE, THE BETTER YOU WILL BE PROTECTED.

CERTIFICATES

Download your certificate of conformance and certificate of irradiation using a secure download service.

COMPLIANCE - COMFORT - PROTECTION

The name of our company, SHIELD Scientific, reflects the particular focus we have on hand protection and the laboratory/high technology sectors.

WWW.SHIELDSCIENTIFIC.COM

is the nerve centre for the dissemination of information. Our website was built to be an interactive tool and a source of information to help users make the right decision.

LEARNING CENTRE

Expand your glove knowledge and understanding through a set of technical articles.

SELECTION GUIDE

Filter either by use, risk or attribute to facilitate your selection of the appropriate glove.

CHEMICAL RESISTANCE GUIDE

Select your chemical, select 1 to 3 gloves, get the breakthrough time: compare and choose.

REGULATIONS & STANDARDS

Understand the Regulations and Standards to satisfy your Health & Safety duties and responsibilities.

DOCUMENTATION

Access from one place to all our product documentation using a free download service.

GLOVE SELECTION GUIDE

With the SHIELD Scientific product colour coding, selecting the

		SHIELDskin CHEM ™	SHIELDskin ™		
	PRODUCT NAME	NEO NITRILE™ 300	ORANGE NITRILE™ 260	ORANGE NITRILE™ 300	ORANGE NITRILE™ 300 Sterile
	PRODUCT CODE	66 925X	67 623X	67 625X	67 635X
	SIZE	6/XS to 11/XXL	6/XS to 10/XL	6/XS to 11/XXL	6/XS to 11/XXL
	GLOVES PER DISPENSER X DISPENSERS PER CARTON (Except sterile gloves)	40 X 10	90 X 10	50 X 10	1 pair/PE peel pouch X 20 pouches per polybag X 8 poly bags/PE bag per carton

REGULATION

Regulation (EU) 2016/425	PERSONAL PROTECTIVE EQUIPMENT	Category III	Category III	Category III	Category III
Regulation (EU) 2017/745	MEDICAL DEVICE	Class 1	Class 1	Class 1	✘
ISO 21420:2020	PPE GLOVES GENERAL REQUIREMENTS	✔	✔	✔	✔
EN 455-2:2015	MEDICAL GLOVES PHYSICAL PROPERTIES	✔	✔	✔	✔

PHYSICAL PROPERTIES

	GLOVE COLOUR				
	MATERIAL	Neoprene/Nitrile	Nitrile/Neoprene	Nitrile/Neoprene	Nitrile/Neoprene
	DESIGN	Ambidextrous	Ambidextrous	Ambidextrous	Ambidextrous
		Textured fingertips	Textured fingertips	Textured fingertips	Textured fingertips
		Powder-free	Powder-free	Powder-free	Powder-free
	ACCELERATOR ALLERGENS	Free of Thiurams	Accelerator-free	Accelerator-free	Accelerator-free
	LATEX PROTEIN ALLERGENS	Latex-free	Latex-free	Latex-free	Latex-free
	TECHNOLOGY PROTECTION	twinSHIELD™	twinSHIELD™	twinSHIELD™	twinSHIELD™
	PALM NOMINAL THICKNESS (mm)	0.31	0.14	0.14	0.14
	PALM NOMINAL THICKNESS (mil)	12.2	5.5	5.5	5.5
	LENGTH (mm)	300	260	300	300
	LENGTH (inch)	11.8	10.2	11.8	11.8

PROTECTION PROPERTIES

		TYPE	A (AJKLNPT)	B (JKPT)	B (JKPT)	B (JKPT)
ISO 374-1:2016+A1:2018	CHEMICAL	PERMEATION (EN 16523-1:2015+A1:2018)	✔	✔	✔	✔
		PENETRATION (ISO 374-2:2019)	✔	✔	✔	✔
		DEGRADATION (ISO 374-4:2019)	✔	✔	✔	✔
ISO 374-5:2016	BIOLOGICAL	VIRUS (ISO 16604:2004 Procedure B)	✔	✔	✔	✔
		BACTERIA, FUNGI (ISO 374-2:2019)	✔	✔	✔	✔
		AQL (Level) (ISO 374-2:2019)	0.25 (Level 3)	0.25 (Level 3)	0.25 (Level 3)	0.25 (Level 3)
EN 388:2016+A1:2018	MECHANICAL	ABRASION, CUT, TEAR, PUNCTURE RESISTANCE	2000X	✘	✘	✘
EN 1149-1/2/3&5	ESD	ELECTROSTATIC PROPERTIES	✔	✔	✔	✔
MO BIO CERTIFICATION	DNase RNase	CONTAMINATION FREE	✘	✘	✘	✔
EN 421:2010	RADIOACTIVITY	RADIOACTIVE CONTAMINATION	✔	✔	✔	✔
ASTM D6978-05 (2019)	CYTOTOXIC DRUG	7+2 DRUGS TESTED	✔	✔	✔	✔

Disclaimer: Being compliant with the standards does not guarantee absolute protection because w

uniSHIELD™ technology

> uniSHIELD™ are single-walled gloves for standard protection.

COMPLIANCE - COMFORT - PROTECTION

"I would like a glove that is both comfortable, protects against all types of hazards and is economic". To date, this is simply technically impossible. Remember that no single glove will provide protection in all applications. The most important factors which need to be considered collectively and not separately are the nature of the hazard, the task, the worker and the workplace environment!

right gloves is now an easy exercise!

ecoSHIELD ™		duoSHIELD ™				
Eco Nitrile PF 250	Eco Latex PF 250	PFT Nitrile 240	PFT Nitrile 290	ICE NITRILE™ 240	PFT Latex 240	LPS Latex 240
62 512X	62 313X	65 812X	65 814X	65 512X	65 412X	65 112X
6/XS to 10/XL	6/XS to 10/XL	6/XS to 10/XL	6/XS to 10/XL	6/XS to 10/XL	6/XS to 10/XL	6/XS to 10/XL
150 X 10	100 X 10	200 X 10	100 X 10	100 X 10	100 X 10	100 X 10
Category III	Category III	Category III	Category III	Category III	Category III	Category III
Class 1	Class 1	Class 1	Class 1	Class 1	Class 1	Class 1
✔	✔	✔	✔	✔	✔	✔
✔	✔	✔	✔	✔	✔	✔
Nitrile	Natural Latex	Nitrile	Nitrile	Nitrile	Natural Latex	Natural Latex
Ambidextrous	Ambidextrous	Ambidextrous	Ambidextrous	Ambidextrous	Ambidextrous	Ambidextrous
Textured fingertips	Smooth finish	Textured fingertips	Textured fingertips	Textured fingertips	Fully textured	Smooth finish
Powder-free	Powder-free	Powder-free	Powder-free	Powder-free	Powder-free	Lightly powdered
Free of Thiazoles and Thiurams	Free of Thiazoles and Thiurams	Free of Thiazoles	TBA	Free of Thiazoles and Thiurams	Free of Thiazoles and Thiurams	Free of Thiurams
Latex-free	≤ 50 µg/g	Latex-free	Latex-free	Latex-free	≤ 50 µg/g	≤ 200 µg/g
twinSHIELD™	uniSHIELD™	uniSHIELD™	uniSHIELD™	uniSHIELD™	uniSHIELD™	uniSHIELD™
0.10	0.16	0.08	0.08	0.11	0.14	0.11
3.9	6.3	3.1	3.1	4.3	5.5	4.3
250	250	240	290	240	240	240
9.8	9.8	9.4	11.4	9.4	9.4	9.4
B (JKPT)	B (KPT)	B (KPT)	B (KPT)	B (KPT)	B (KPT)	B (KPT)
✔	✔	✔	✔	✔	✔	✔
✔	✔	✔	✔	✔	✔	✔
✔	✔	✔	✔	✔	✔	✔
✔	✔	✔	✔	✔	✔	✔
✔	✔	✔	✔	✔	✔	✔
0.25 (Level 3)	0.65 (Level 3)	0.65 (Level 3)	0.65 (Level 3)	1.5 (Level 2)	1.5 (Level 2)	1.5 (Level 2)
✘	✘	✘	✘	✘	✘	✘
✔	✘	✘	✘	✘	✘	✘
✘	✘	✘	✘	✘	✘	✘
✔	✔	✔	✔	✔	✔	✔
✘	✘	✘	✘	✘	✘	✘

What is tested relates to the materials used, methods of manufacture, length and thickness of the glove.

twinSHIELD™ technology

- twinSHIELD™ are double-walled gloves for double protection.
- Double dipping: to reduce the risk of pinholes and to improve the level of barrier protection.
- Double layer: a white, softer and more comfortable inner layer with a coloured outer layer to identify the type of risk (Traffic light: Green, Orange or Red).

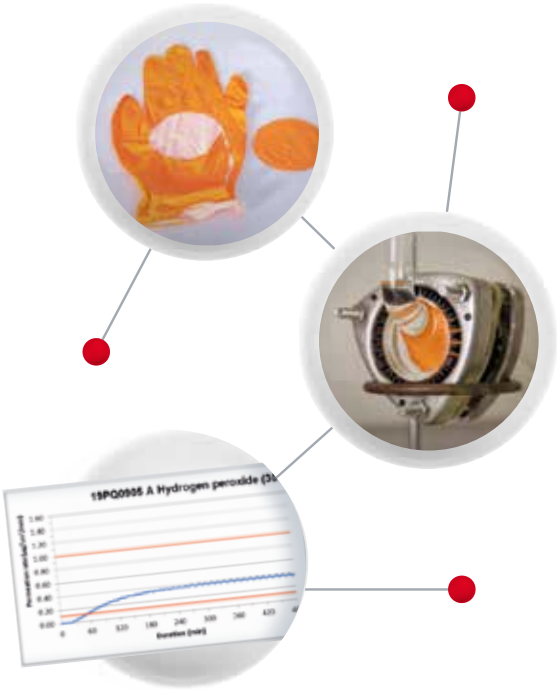
SHIELDskin CHEM™

CHEMICAL RISK

In response to user demand for a glove offering a higher level of protection in the laboratory but without compromising dexterity and comfort, SHIELD Scientific has developed the SHIELDskin CHEM™ range of gloves. The twinSHIELD™ technology provides double-walled barrier protection: two materials, two layers and two colours. Apart from being registered according to Regulation (EU) 2016/425 as Personal Protective Equipment Category III (Complex Design), SHIELDskin CHEM™ gloves are type A and as such offer the highest level of chemical protection. In this respect, the gloves have achieved a minimum breakthrough time of thirty minutes in at least six of the eighteen chemicals listed in ISO 374-1:2016+A1:2018.

PERMEATION TEST METHOD

The permeation break through time is determined according to the EN 16523 1:2015+A1:2018 and is a useful method for evaluating the barrier effectiveness of a glove against liquid chemicals under laboratory conditions and at room temperature (+/- 23°C). It measures how quickly a liquid chemical moves through the glove material at the molecular level. The normalised permeation rate is defined as 1µg/min/cm² and the maximum duration for the test is 480 minutes.



> STEP 1: 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 chemical risks, then three additional test specimens shall be taken from the cuff area.

> STEP 2: 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: The breakthrough time is deemed to have occurred when the permeation rates of the challenge chemical reaches the normalized permeation rate (1µg/min/cm²). The result is then reported in minutes.

It should be noted that a higher ambient temperature or higher chemical concentrations can make the breakthrough time shorter. Therefore, it may be prudent to give yourself a safety margin in terms of deciding when to discard gloves and replace them with new ones!

In the table below you'll see the performance for three of our synthetic gloves based on EN 16523-1:2015+A1:2018. On paper they

Chemical name	CAS N°	Concentration	SHIELDskin CHEM™ NEO NITRILE™ 300	SHIELDskin™ ORANGE NITRILE™ 260	ecoSHIELD™ Eco Nitrile PF 250
Thickness (Palm)			**0.31 mm**	**0.14 mm**	**0.10 mm**
Sodium acetate Sat. solution	127-09-3	100%	480 min	480 min	480 min
Acrylamide	79-06-1	40%	480 min	480 min	480 min
Ethidium bromide	1239-45-8	5%	480 min	480 min	480 min
Formaldehyde	50-00-0	37%	480 min	480 min	480 min
Sodium hydroxide	1310-73-2	40%	480 min	480 min	480 min
Tris (hydroxymethyl) aminomethane Sat. solution	77-86-1	100%	480 min	480 min	480 min
Hydrochloric acid	7647-01-0	37%	480 min	130 min	98 min
Isobutanol	78-83-1	99%	480 min	76 min	39 min
Isopropanol	67-63-0	66%	480 min	66 min	58 min
Secondary isoamyl alcohol	598-75-4	98%	480 min	55 min	30 min

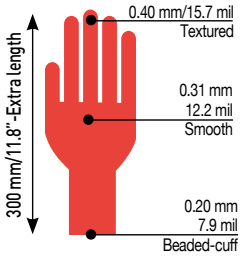
FOR HANDS THAT NEED EXTRA PROTECTION

THE THICKER AND LONGER THE GLOVE,
THE BETTER YOU WILL BE PROTECTED

twinSHIELD™

AQL 0.25

SHIELDskin CHEM™ NEO NITRILE™ 300



Powder-free • Non-sterile

MATERIAL	COLOUR	DESIGN	ALLERGIES
Neoprene/ Nitrile	Red (outer) White (inner)	Ambidextrous Textured fingertips	Free of Thiurams Latex-free

Size	6/XS	7/S	8/M	9/L	10/XL	11/XXL
Code	66 9251	66 9252	66 9253	66 9254	66 9255	66 9256

40 gloves/dispenser — 10 dispensers/carton

PPE Personal Protective Equipment Category III REGULATION (EU) 2016/425 · MDR Medical Device Class I REGULATION (EU) 2017/745 · CE 0598

all comply with the same standards, but as you will notice they do not offer the same level of performance!

Chemical name	CAS N°	Concentration	SHIELDskin CHEM™ NEO NITRILE™ 300	SHIELDskin™ ORANGE NITRILE™ 260	ecoSHIELD™ Eco Nitrile PF 250
Dimethyl sulfoxide (DMSO)	67-68-5	99%	179 min	48 min	10 min
Phenol	108-95-2	50%	163 min	23 min	15 min
Ethanol	64-17-5	99.8%	154 min	20 min	9 min
Formic acid	64-18-6	98.5%	125 min	4 min	Immediate
Formamide	75-12-7	99%	123 min	99 min	11 min
Acetic acid	64-19-7	99%	81 min	7 min	4 min
Methanol	67-56-1	99.9%	36 min	5 min	Immediate
Dimethyl formamide (DMF)	68-12-2	99.8%	9 min	4 min	1 min
Xylene	1330-20-7	98.5%	8 min	4 min	2 min
Chloroform	67-66-3	99.8%	4 min	Immediate	Immediate

DISCLAIMER: The data provided was based on gloves tested under laboratory conditions, in accordance with EN 16523-1:2015+A1:2018. The information is for guidance only and may not reflect the user's application. A risk assessment should always be made by purchaser to assess the suitability of gloves for a specific application. For more data, please see our online Chemical resistance guide on our website www.shieldscientific.com.

SHIELDskin™

BIOLOGICAL RISK

For the purposes of providing protection against biological hazards, the glove must comply with the European Standard ISO 374-5:2016 "Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks". The standard differentiates between gloves offering protection against bacteria plus fungi (micro-organisms resistant) and those which additionally provide protection against viruses.

MICRO-ORGANISMS RESISTANT

To evaluate the barrier resistance of a glove against bacteria and fungi, a liquid penetration test is undertaken according to ISO 374-2:2019. Gloves are filled with water and when a leak is detected, water droplets appear on the outside of the glove. As not all the gloves in a batch can be tested, statistical probability is used based on the AQL level.

> **STEP 1:** Select the AQL and Inspection Level.

Performance Levels	Acceptable Quality Levels (AQL)	Inspection Levels
Level 3	< 0.65	G1
Level 2	< 1.5	G1
Level 1	< 4.0	S4

> **STEP 2:** Define the number of samples to be tested according to the batch size and inspection level (Standard ISO 2859-1:1999). On the assumption that a typical production lot of gloves is between 150 000 and 500 000 gloves, then, the number of samples to be evaluated is either 315 for PPE gloves or 200 for MDR gloves (EN 455-1:2000).

> **STEP 3:** Each glove sample is filled with one litre of water. After 30 seconds, if there is no leak then the sample passes. If a leak is detected, then it fails.

PENETRATION TEST METHOD

As can be seen in the table below, there is always an inherent risk of pinholes in glove manufacturing. Indeed the higher the AQL, the more gloves failures are permitted. In this context, it will be noted that with a sample size of 315, up to 21 gloves could have pinholes and still pass. In contrast, an AQL of 0.25 means that only up to two gloves could have pinholes.

SAMPLES	AQL 4.0	AQL 1.5	AQL 0.65	AQL 0.25
Number of gloves tested	315	315	315	315
PASS (Gloves - %)	21 6.67%	10 3.17%	5 1.59%	2 0.63%
FAIL (Gloves - %)	22 6.98%	11 3.49%	6 1.90%	3 0.95%

VIRUS RESISTANT

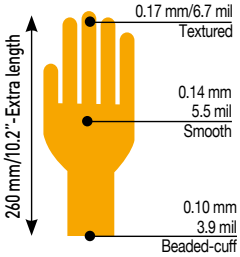
ISO 16604:2004 Procedure B evaluates the barrier resistance of a glove to penetration by viruses. Three tests specimens are subjected to a nutrient broth containing Phi-X174 bacteriophage in a test apparatus for a specified time and pressure sequence (0 kPa for 5 min, followed by 14 kPa for 1 min and finally 0 kPa for 4 min). Visual detection of penetration is supplemented with an assay procedure that will detect viable viruses which penetrate the material even when liquid penetration is not visible. Any evidence of viral penetration for a test specimen constitutes a failure.

Test specimen	Number of PFU/ml of assay fluid	Pass/Fail Result
# Sample 1	< 1	Pass
# Sample 2	< 1	Pass
# Sample 3	< 1	Pass

COMPLIANCE - COMFORT - PROTECTION

THE LOWER THE AQL,
THE BETTER YOU WILL BE PROTECTED

SHIELDskin™ ORANGE NITRILE™ 260



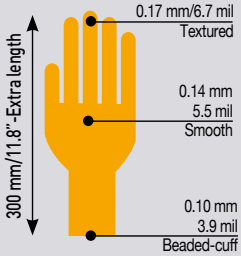
Powder-free • Non-sterile

MATERIAL	COLOUR	DESIGN	ALLERGIES
Nitrile/ Neoprene	Orange (outer) White (inner)	Ambidextrous Textured fingertips	Accelerator-free Latex-free

Size	6/XS	7/S	8/M	9/L	10/XL
Code	67 6231	67 6232	67 6233	67 6234	67 6235

90 gloves/dispenser — 10 dispensers/carton

SHIELDskin™ ORANGE NITRILE™ 300



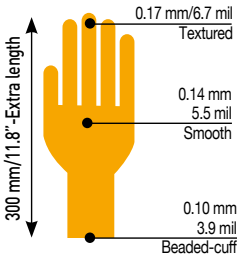
Powder-free • Non-sterile

MATERIAL	COLOUR	DESIGN	ALLERGIES
Nitrile/ Neoprene	Orange (outer) White (inner)	Ambidextrous Textured fingertips	Accelerator-free Latex-free

Size	6/XS	7/S	8/M	9/L	10/XL	11/XXL
Code	67 6251	67 6252	67 6253	67 6254	67 6255	67 6256

50 gloves/dispenser — 10 dispensers/carton

SHIELDskin™ ORANGE NITRILE™ 300 Sterile



Powder-free • Sterile

MATERIAL	COLOUR	DESIGN	ALLERGIES
Nitrile/ Neoprene	Orange (outer) White (inner)	Ambidextrous Textured fingertips	Accelerator-free Latex-free

Size	6/XS	7/S	8/M	9/L	10/XL	11/XXL
Code	67 6351	67 6352	67 6353	67 6354	67 6355	67 6356

1 pair/PE peel pouch — 20 pairs/sealed poly bag — 8 poly bags/carton

ecoSHIELD™ GENERAL RISK

Increasingly we are seeking greener solutions for the working environment. That's why we created packaging that takes into account the material used, recyclability, savings on storage space and the need for fewer deliveries.

ecoSHIELD™ your environmental ally

> Manufactured from recycled cardboard. The use of recycled cardboard reduces by half CO_2 emissions per kg of produced cardboard.

> Simple design, providing a natural look. The amount of printing on the packaging has been reduced by over 60% on the dispenser. The de-inking stage of the recycling process can be the most polluting part.

> Limited use of surface transport in favour of maritime transport. Elimination of air transport, which is known to be ten times more polluting.

Focus on ecoSHIELD™ Eco Nitrile PF 250

> Improved design means that 50% more gloves can be packaged in the same volume.

> With the packaging of ecoSHIELD™ Eco Nitrile PF 250 gloves, we save more than 30% carboard. This represents half a tree for every million gloves packed.

> Shortening of the supply chain which contributes to a 700kg reduction in CO_2 emissions for every 1000 cartons delivered.

> Reduced storage space.

RECYCLE
"Recycled cardboard and 60% less printing"

FREIGHT
"Maritime freight and shorter supply chain"

STORAGE*
"50% more gloves in a dispenser"

APPLICATION
"The right glove for the right task"

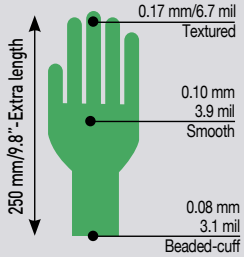
INCINERATION
"Glove source of energy"

*ecoSHIELD™ Eco Nitrile PF 250 only.

COMPLIANCE - COMFORT - PROTECTION

BEST COMPROMISE BETWEEN PERSONAL
AND ENVIRONMENTAL PROTECTION

ecoSHIELD™ Eco Nitrile PF 250



Powder-free • Non-sterile

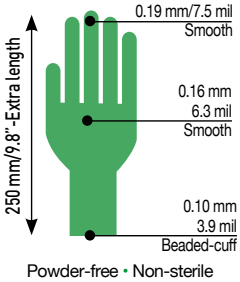
MATERIAL	COLOUR	DESIGN	ALLERGIES
Nitrile	Green (outer) White (inner)	Ambidextrous Textured fingertips	Free of Thiazoles and Thiurams Latex-free

Size	6/XS	7/S	8/M	9/L	10/XL
Code	62 5121	62 5122	62 5123	62 5124	62 5125

150 gloves/dispenser — 10 dispensers/carton

PPE Personal Protective Equipment Category III REGULATION (EU) 2016/425 · MDR Medical Device Class I REGULATION (EU) 2017/745 · CE 0598 · ISO 374-1 Type B JKPT · ISO 374-5:2016 Level 3 VIRUS

ecoSHIELD™ Eco Latex PF 250



Powder-free • Non-sterile

MATERIAL	COLOUR	DESIGN	ALLERGIES
Natural Rubber Latex	Natural colour	Ambidextrous Smooth finish	Free of Thiazoles and Thiurams Low protein level

Size	6/XS	7/S	8/M	9/L	10/XL
Code	62 3131	62 3132	62 3133	62 3134	62 3135

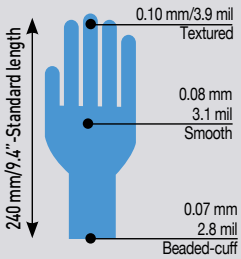
100 gloves/dispenser — 10 dispensers/carton

PPE Personal Protective Equipment Category III REGULATION (EU) 2016/425 · MDR Medical Device Class I REGULATION (EU) 2017/745 · CE 0598 · ISO 374-1 Type B KPT · ISO 374-5:2016 Level 3 VIRUS · LATEX

duoSHIELD™
DUAL RISK

The duoSHIELD™ range of gloves offer an excellent solution for laboratory personnel seeking protection against limited risks at the best optimal cost. Likewise, these gloves fulfil the growing need for increased protection of patients and medical staff in the health sector, hence the reference to "duo" or dual protection. The duoSHIELD™ gloves are dual registered: Class 1 Medical Devices according to Regulation (EU) 2017/745 and Personal Protective Equipment Category III (Complex Design) according to Regulation (EU) 2016/425. They are tested against the latest medical devices (EN 455-1:2000, EN 455-2:2015, EN 455-3:2015 and EN 455-4:2009) and Personal Protective Equipment standards (ISO 21420:2020, ISO 374-1:2016+A1:2018 and ISO 374-5:2016).

duoSHIELD™ PFT Nitrile 240



Powder-free • Non-sterile

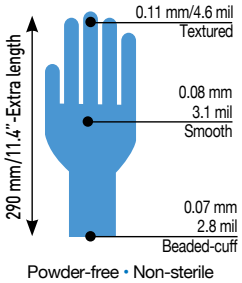
MATERIAL	COLOUR	DESIGN	ALLERGIES
Nitrile	Blue	Ambidextrous Textured fingertips	Free of Thiazoles Latex-free

Size	6/XS	7/S	8/M	9/L	10/XL
Code	65 8121	65 8122	65 8123	65 8124	65 8125

200 gloves/dispenser — 10 dispensers/carton

PPE Personal Protective Equipment Category III REGULATION (EU) 2016/425 · MDR Medical Device Class I REGULATION (EU) 2017/745 · CE 0598 · ISO 374-1 Type B KPT · ISO 374-5:2016 Level 3 VIRUS

duoSHIELD™ PFT Nitrile 290



Powder-free • Non-sterile

MATERIAL	COLOUR	DESIGN	ALLERGIES
Nitrile	Blue	Ambidextrous Textured fingertips	Latex-free

Size	6/XS	7/S	8/M	9/L	10/XL
Code	65 8141	65 8142	65 8143	65 8144	65 8145

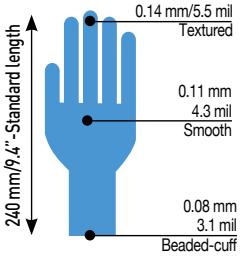
100 gloves/dispenser — 10 dispensers/carton

PPE Personal Protective Equipment Category III REGULATION (EU) 2016/425 · MDR Medical Device Class I REGULATION (EU) 2017/745 · CE 0598 · ISO 374-1 Type B KPT · ISO 374-5:2016 Level 3 VIRUS

COMPLIANCE - COMFORT - PROTECTION

DUAL REGISTRATION FOR PERSONNEL
AND PATIENT PROTECTION

duoSHIELD™ ICE NITRILE™ 240



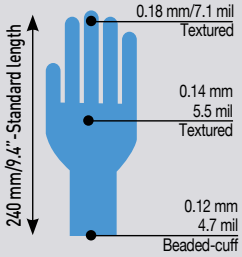
MATERIAL	COLOUR	DESIGN	ALLERGIES
Nitrile	Ice blue	Ambidextrous Textured fingertips	Free of Thiazoles and Thiurams Latex-free

Size	6/XS	7/S	8/M	9/L	10/XL
Code	65 5121	65 5122	65 5123	65 5124	65 5125

100 gloves/dispenser — 10 dispensers/carton

Powder-free • Non-sterile

duoSHIELD™ PFT Latex 240



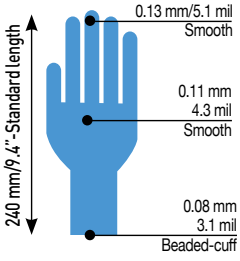
MATERIAL	COLOUR	DESIGN	ALLERGIES
Natural Rubber Latex	Natural colour	Ambidextrous Fully textured	Free of Thiazoles and Thiurams Low protein level

Size	6/XS	7/S	8/M	9/L	10/XL
Code	65 4121	65 4122	65 4123	65 4124	65 4125

100 gloves/dispenser — 10 dispensers/carton

Powder-free • Non-sterile

duoSHIELD™ LPS Latex 240



MATERIAL	COLOUR	DESIGN	ALLERGIES
Natural Rubber Latex	Natural colour	Ambidextrous Smooth finish	Free of Thiurams

Size	6/XS	7/S	8/M	9/L	10/XL
Code	65 1121	65 1122	65 1123	65 1124	65 1125

100 gloves/dispenser — 10 dispensers/carton

Lightly powdered • Non-sterile

UNDERSTANDING DISPOSABLE GLOVE REGULATIONS AND STANDARDS

REGULATIONS AND STANDARDS

RELATING TO GLOVES	SCOPE
Regulation (EU) 2016/425	General requirements for the design and manufacture of Personal Protective Equipment (PPE).

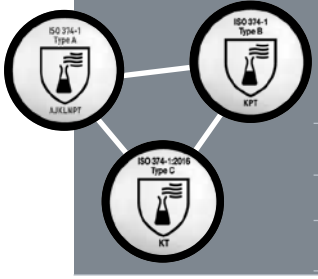
GLOVE CATEGORY	RISK LEVEL	MARKING
Category I	For minimal risks only.	CE
Category II	For risks other than those listed in cat. I & III.	CE
Category III	For risks that may cause very serious consequences such as death or irreversible damage to health.	CE + Notified Body CE 0598

Regulation (EU) 2017/745	Medical Devices Regulation.
ISO 21420:2020	Protective gloves - General requirements and test methods. This standard defines the general requirements and relevant test procedures for glove design and construction, resistance of glove materials to water penetration, innocuousness, comfort and efficiency, marking and information supplied by the manufacturer applicable to all protective gloves.

CHEMICAL RISK

STANDARDS 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.
ISO 374-2:2019	Protective gloves against dangerous chemicals and micro-organisms. Part 2: Determination of resistance to penetration.
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 374-4:2019	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).



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

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

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BIOLOGICAL RISK

STANDARDS 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 (Procedure B) using the bacteriophage penetration test.

MECHANICAL RISK

STANDARDS REFERENCE	SCOPE
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.

Abrasion resistance (PF* 1 to 4)
Cut resistance (coupe test) (PF* 1 to 5)
Tear resistance (PF* 1 to 4)
Puncture resistance (PF* 1 to 4)
Cut resistance (PF* 1 to 4)

If one of these characters is replaced with an "X", it means that the test has either not been performed or is not applicable.
**PF: Performance Level.*

RADIOACTIVE CONTAMINATION RISK

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

MEDICAL USE

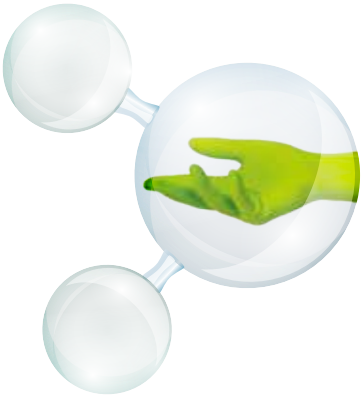
STANDARDS REFERENCE	SCOPE
EN 455-1:2000	Medical gloves for single use. Part 1: Requirements and testing for freedom from holes.
EN 455-2:2015	Medical gloves for single use. Part 2: Requirements and testing for physical properties.
EN 455-3:2015	Medical gloves for single use. Part 3: Requirements and testing for biological evaluation.
EN 455-4:2009	Medical gloves for single use. Part 4: Requirements and testing for shelf-life determination.

CHEMICAL RISK

BIOLOGICAL RISK

GENERAL RISK

DUAL RISK



SHIELD Scientific
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