

# CLEANROOM GLOVES

# 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 longterm partnerships where the emphasis is on mutual gain.

# COMPLIANCE

Following the introduction of Regulation (EU) 2016/425, SHIELD Scientific remains at the forefront offering cleanroom 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

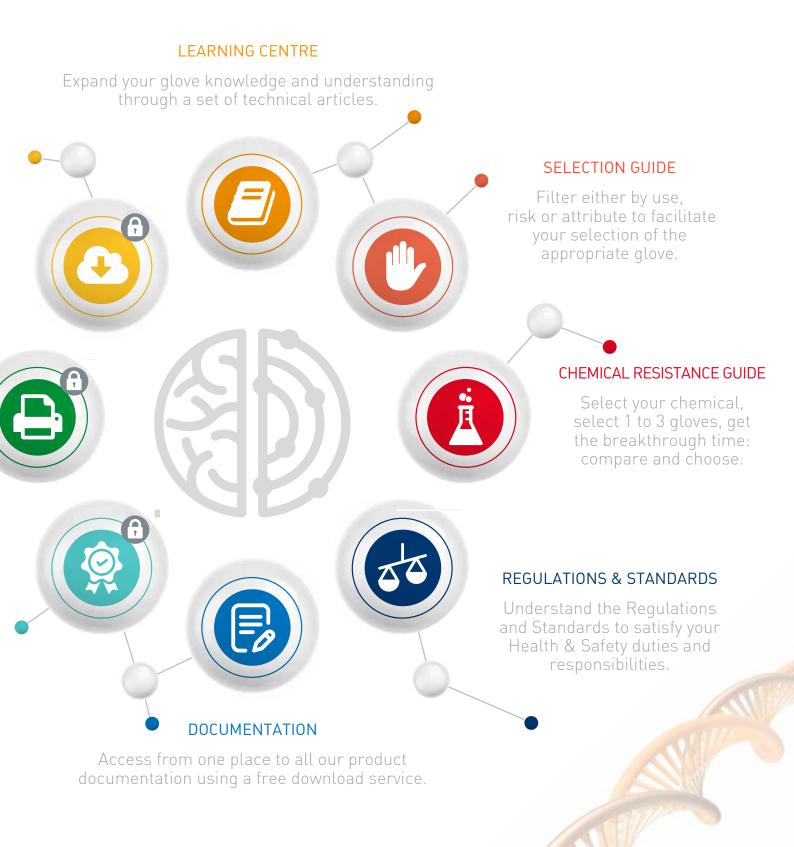
Download your certificate of conformance and certificate of irradiation using a secure download service.



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.



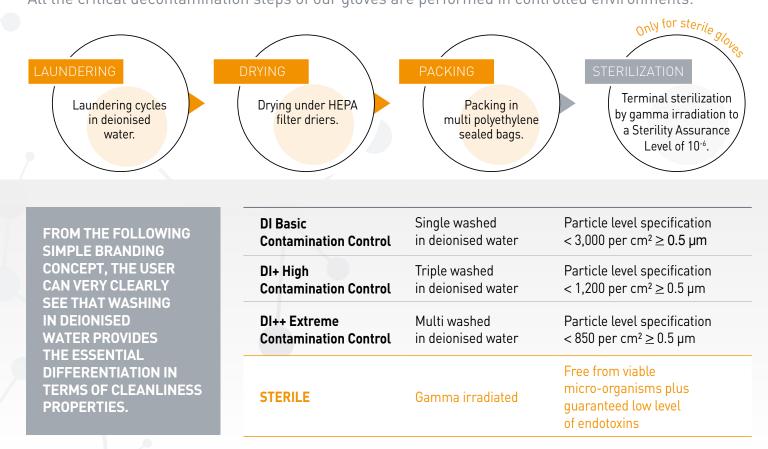
# **GLOVES CONTAMINATION CONTROL EXPE**

# FOR PERSONAL, PROCESS AND PRODUCT PROTECTION

Selecting cleanroom gloves is typically a long process. Even if personal safety is an important priority, maintaining the cleanliness of the environment is the primary purpose for wearing gloves to avoid contamination of the product.

#### **CONTAMINATION CONTROL IN OUR GLOVES**

All the critical decontamination steps of our gloves are performed in controlled environments:



#### PERSONAL PROTECTION AND COMFORT

**PPE Regulation:** All our SHIELDskin XTREME<sup>™</sup> gloves are registered as Personal Protective Equipment Category III (Complex design) as defined in the Regulation (EU) 2016/425.

**Chemical protection:** Thicker and longer gloves provide extra protection against chemicals. Visit our online chemical resistance guide with over 100 chemicals tested against chemical permeation (EN 16523-1:2015+A1:2018).

**Cytotoxic substances protection:** To respond to the need for greater personal protection when handling cytotoxic substances, we were amongst the first companies in Europe to promote testing of gloves against ASTM D6978-05 (2019) rather than the less stringent EN 16523-1:2015+A1:2018.

**Dexterity and comfort:** Our aim is to supply gloves that satisfy the wellbeing of users, without compromising skin care and protection. Our SHIELDskin XTREME<sup>™</sup> gloves are powder-free and are either accelerator-free or low in chemical residues to reduce glove-associated reactions.



#### **PROCESS AND PRODUCT PROTECTION**

#### PARTICLE AND EXTRACTABLE LEVELS:

SHIELDskin XTREME™ gloves undergo deionised water laundering cycles to achieve low level of particles, extractable ions and nonvolatile residues, which is crucial within the cleanroom manufacturing environment.

#### **ESD SOLUTIONS:**

SHIELDskin XTREME™ synthetic gloves have been tested according EN 1149-1/2/3/5 (test methods for measurement of electrostatic properties) to address concerns regarding environmental and process protection.

#### THE LOWER THE ACCEPTABLE QUALITY LEVEL (AQL), THE HIGHER THE LEVEL OF BARRIER PERFORMANCE IN TERMS OF REDUCED RISK OF PINHOLES.

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

SHIELDskin™

#### **BIO CONTAMINATION PROTECTION:**

SHIELDskin XTREME™ gloves provide superior process and personal protection from liquid penetration (ISO 374-2:2019). Gloves are tested for viral penetration resistance using a Phi-X174 bacteriophage (ISO 16604:2004 Procedure B). Gloves are gamma irradiated to meet the highest level of contamination control required by specific industries working in aseptic environment.



#### DOCUMENTATION

# Product Data Sheet (PDS):

Details on the specifications and performance of SHIELDskin XTREME™ gloves are outlined in the Product Data Sheet, which is readily accessible from our website.

#### Certificate of Conformance (CoC):

As a guarantee of industry leading performance, SHIELD Scientific provides Certificate of Conformance with lot-specific data such as particles and extractables. For sterile gloves, test data on endotoxin levels is also presented.

#### Certificate of Irradiation (Col):

As SHIELDskin XTREME™ sterile gloves are terminally sterilised by gamma irradiation to a Sterility Assurance Level (SAL) of 10<sup>-6</sup> (ISO 11137-2:2015), SHIELD Scientific provides a Certificate of Irradiation for each lot of sterile gloves.

# Contamination data monitoring:

SHIELD Scientific aims to provide the most comprehensive and accurate statistical data to demonstrate the consistency of contamination control performance.

#### WWW.SHIELDSCIENTIFIC.COM

# **GLOVE SELECTION GUIDE**

## With the SHIELD Scientific product brand code, pre-selecting

		SHIELDskin Xtreme	ORANGE NITRILE™ 300 DI		Eco Nitrile 300 DI+	White Nitrile 400
		PRODUCT CODE	69 645X	69 845X	68 865X	69 867X
		SIZE	6/XS to 11/XXL	6/XS to 11/XXL	6/XS to 11/XXL	6/XS to 11/XXL
	GLOVES PER PE	BAG X BAG per POLYBAG X POLYBAG PER CARTON (For non-sterile gloves)	100 X 10 X 1	100 X 10 X 1	100 X 15 X 1	100 X 10 X 1
		IVES PAIR POUCH PER POLYBAG X POLYBAG PER CASE (For sterile gloves)				
REGULATIO	N					
Regulation (EU) 2016/425		PERSONAL PROTECTIVE EQUIPMENT	Category III	Category III	Category III	Category III
50 21420:2020		PPE GLOVES GENERAL REQUIREMENTS	V	V	V	v .
EN 455-2:2015		MEDICAL GLOVES PHYSICAL PROPERTIES	V	V	V	<ul> <li>✓</li> </ul>
HYSICAL P	PROPERTIE					
		GLOVE COLOUR		A175 71	A17. 71	
		MATERIAL	Nitrile/Neoprene	Nitrile	Nitrile	Nitrile
			Ambidextrous	Ambidextrous	Ambidextrous	Ambidextrou
		DESIGN	Textured fingertips	Textured fingertips	Textured fingertips	Textured palm fingers
			Powder-free	Powder-free	Powder-free	Powder-fre
		ACCELERATOR ALLERGENS	Accelerator-free	Free of Thiurams and Thiazoles	Free of Thiurams and Thiazoles	Free of Thiura and Thiazole
		LATEX PROTEIN ALLERGENS	Latex-free	Latex-free	Latex-free	Latex-free
		TECHNOLOGY PROTECTION	twinSHIELD™	uniSHIELD™	uniSHIELD™	uniSHIELD <sup>1</sup>
		PALM NOMINAL THICKNESS (mm)	0.14	0.13	0.10	0.15
		PALM NOMINAL THICKNESS (mil)	5.5	5.1	3.9	5.9
		PALM NOMINAL THICKNESS (mil) LENGTH (mm)	5.5 300	5.1 300	3.9 300	5.9 400
		LENGTH (mm) LENGTH (inch)	300	300	300	400
LEANLINE	SS PROPER	LENGTH (mm) LENGTH (inch)	300 11.8	300 11.8	300 11.8	400 15.7
LEANLINE	SS PROPER	LENGTH (mm) LENGTH (inch) RTIES CONTAMINATION CONTROL LEVEL	300 11.8 BASIC	300 11.8 BASIC	300 11.8 HIGH	400 15.7 HIGH
LEANLINE	CONTAMINATION	LENGTH (mm) LENGTH (inch) RTIES CONTAMINATION CONTROL LEVEL CONTAMINATION CONTROL PROCESS	300 11.8 BASIC Single washed DI	300 11.8 BASIC Single washed DI	300 11.8 HIGH Triple washed DI	400 15.7 HIGH Triple washed
	_	LENGTH (mm) LENGTH (inch) RTIES CONTAMINATION CONTROL LEVEL CONTAMINATION CONTROL PROCESS CONTAMINATION SPECIFICATION PARTICLES LEVEL	300 11.8 BASIC Single washed DI < 3,000 particles	300 11.8 BASIC Single washed DI < 3,000 particles	300 11.8 HIGH Triple washed DI < 1,200 particles	400 15.7 HIGH Triple washed < 1,200 partic
	CONTAMINATION	LENGTH (mm) LENGTH (inch) RTIES CONTAMINATION CONTROL LEVEL CONTAMINATION CONTROL PROCESS CONTAMINATION SPECIFICATION PARTICLES LEVEL CONTAMINATION TYPICAL PARTICLES VALUE	300 11.8 BASIC Single washed DI < 3,000 particles 2,100 particles	300 11.8 BASIC Single washed DI < 3,000 particles 2,300 particles	300 11.8 HIGH Triple washed DI < 1,200 particles 1,100 particles	400 15.7 HIGH Triple washed < 1,200 particle 1,000 particle
	CONTAMINATION	LENGTH (mm) LENGTH (inch) RTIES CONTAMINATION CONTROL LEVEL CONTAMINATION CONTROL PROCESS CONTAMINATION SPECIFICATION PARTICLES LEVEL CONTAMINATION TYPICAL PARTICLES VALUE NON-VOLATILE RESIDUE	300 11.8 BASIC Single washed DI < 3,000 particles 2,100 particles < 30 µg/g	300 11.8 BASIC Single washed DI < 3,000 particles 2,300 particles < 30 μg/g	300 11.8 HIGH Triple washed DI < 1,200 particles 1,100 particles < 30 μg/g	400 15.7 HIGH Triple washed < 1,200 particl 1,000 particl < 30 μg/g
EST-RP-CC005.4	CONTAMINATION	LENGTH (mm) LENGTH (inch) RTIES CONTAMINATION CONTROL LEVEL CONTAMINATION CONTROL PROCESS CONTAMINATION SPECIFICATION PARTICLES LEVEL CONTAMINATION TYPICAL PARTICLES VALUE NON-VOLATILE RESIDUE SILICONE, AMIDE, DOP LEVEL	300 11.8 BASIC Single washed DI < 3,000 particles 2,100 particles < 30 µg/g Non detectable level	300 11.8 BASIC Single washed DI < 3,000 particles 2,300 particles < 30 μg/g Non detectable level	300 11.8 HIGH Triple washed DI < 1,200 particles 1,100 particles < 30 μg/g Non detectable level	400 15.7 HIGH Triple washed < 1,200 partic 1,000 particl < 30 μg/g Non detectable
EST-RP-CC005.4 50 11137-2:2015	CONTAMINATION NVR FTIR STERILITY	LENGTH (mm) LENGTH (inch) RTIES CONTAMINATION CONTROL LEVEL CONTAMINATION CONTROL PROCESS CONTAMINATION SPECIFICATION PARTICLES LEVEL CONTAMINATION TYPICAL PARTICLES VALUE NON-VOLATILE RESIDUE SILICONE, AMIDE, DOP LEVEL STERILITY ASSURANCE LEVEL	300 11.8 BASIC Single washed DI < 3,000 particles 2,100 particles < 30 μg/g Non detectable level N/A	300 11.8 BASIC Single washed DI < 3,000 particles 2,300 particles < 30 μg/g Non detectable level N/A	300 11.8 HIGH Triple washed DI < 1,200 particles 1,100 particles < 30 μg/g Non detectable level N/A	400 15.7 HIGH Triple washed < 1,200 partic 1,000 particl < 30 μg/g Non detectable N/A
ST-RP-CC005.4 50 11137-2:2015 N 455-3:2015	CONTAMINATION NVR FTIR STERILITY ENDOTOXINS	LENGTH (mm) LENGTH (inch) RTIES CONTAMINATION CONTROL LEVEL CONTAMINATION CONTROL PROCESS CONTAMINATION SPECIFICATION PARTICLES LEVEL CONTAMINATION TYPICAL PARTICLES VALUE NON-VOLATILE RESIDUE SILICONE, AMIDE, DOP LEVEL STERILITY ASSURANCE LEVEL ENDOTOXINS LEVEL	300 11.8 BASIC Single washed DI < 3,000 particles 2,100 particles < 30 µg/g Non detectable level N/A N/A	300 11.8 BASIC Single washed DI < 3,000 particles 2,300 particles < 30 µg/g Non detectable level N/A N/A	300 11.8 HIGH Triple washed DI < 1,200 particles 1,100 particles < 30 µg/g Non detectable level N/A N/A	400 15.7 HIGH Triple washee < 1,200 particl 30 µg/g Non detectable N/A N/A
EST-RP-CC005.4 50 11137-2:2015 N 455-3:2015	CONTAMINATION NVR FTIR STERILITY	LENGTH (mm) LENGTH (inch) RTIES CONTAMINATION CONTROL LEVEL CONTAMINATION CONTROL PROCESS CONTAMINATION SPECIFICATION PARTICLES LEVEL CONTAMINATION TYPICAL PARTICLES VALUE NON-VOLATILE RESIDUE SILICONE, AMIDE, DOP LEVEL STERILITY ASSURANCE LEVEL	300 11.8 BASIC Single washed DI < 3,000 particles 2,100 particles < 30 μg/g Non detectable level N/A	300 11.8 BASIC Single washed DI < 3,000 particles 2,300 particles < 30 μg/g Non detectable level N/A	300 11.8 HIGH Triple washed DI < 1,200 particles 1,100 particles < 30 μg/g Non detectable level N/A	400 15.7 HIGH Triple washed < 1,200 particl 2,30 μg/g Non detectable N/A
EST-RP-CC005.4 50 11137-2:2015 :N 455-3:2015 :N 1149-1/2/3&5	CONTAMINATION NVR FTIR STERILITY ENDOTOXINS ESD	LENGTH (mm) LENGTH (inch) RTIES CONTAMINATION CONTROL LEVEL CONTAMINATION CONTROL PROCESS CONTAMINATION SPECIFICATION PARTICLES LEVEL CONTAMINATION TYPICAL PARTICLES VALUE NON-VOLATILE RESIDUE SILICONE, AMIDE, DOP LEVEL STERILITY ASSURANCE LEVEL ENDOTOXINS LEVEL ELECTROSTATIC PROPERTIES	300 11.8 BASIC Single washed DI < 3,000 particles 2,100 particles < 30 µg/g Non detectable level N/A N/A	300 11.8 BASIC Single washed DI < 3,000 particles 2,300 particles < 30 µg/g Non detectable level N/A N/A	300 11.8 HIGH Triple washed DI < 1,200 particles 1,100 particles < 30 µg/g Non detectable level N/A N/A	400 15.7 HIGH Triple washee < 1,200 particl 30 µg/g Non detectable N/A N/A
EST-RP-CC005.4 50 11137-2:2015 N 455-3:2015 N 1149-1/2/3&5	CONTAMINATION NVR FTIR STERILITY ENDOTOXINS	LENGTH (mm) LENGTH (inch) RTIES CONTAMINATION CONTROL LEVEL CONTAMINATION CONTROL PROCESS CONTAMINATION SPECIFICATION PARTICLES LEVEL CONTAMINATION TYPICAL PARTICLES VALUE NON-VOLATILE RESIDUE SILICONE, AMIDE, DOP LEVEL STERILITY ASSURANCE LEVEL ENDOTOXINS LEVEL ELECTROSTATIC PROPERTIES	300 11.8 BASIC Single washed DI < 3,000 particles 2,100 particles < 30 µg/g Non detectable level N/A N/A	300 11.8 BASIC Single washed DI < 3,000 particles 2,300 particles < 30 µg/g Non detectable level N/A N/A	300 11.8 HIGH Triple washed DI < 1,200 particles 1,100 particles < 30 µg/g Non detectable level N/A N/A	400 15.7 HIGH Triple washed < 1,200 particl 1,000 particl < 30 µg/g Non detectable N/A N/A
EST-RP-CC005.4 50 11137-2:2015 N 455-3:2015 N 1149-1/2/3&5 ROTECTIO	CONTAMINATION NVR FTIR STERILITY ENDOTOXINS ESD N PROPER	LENGTH (mm) LENGTH (inch) RTIES CONTAMINATION CONTROL LEVEL CONTAMINATION CONTROL PROCESS CONTAMINATION SPECIFICATION PARTICLES LEVEL CONTAMINATION TYPICAL PARTICLES VALUE NON-VOLATILE RESIDUE SILICONE, AMIDE, DOP LEVEL STERILITY ASSURANCE LEVEL ENDOTOXINS LEVEL ELECTROSTATIC PROPERTIES	300 11.8 BASIC Single washed DI < 3,000 particles 2,100 particles < 30 µg/g Non detectable level N/A N/A	300 11.8 BASIC Single washed DI < 3,000 particles 2,300 particles < 30 µg/g Non detectable level N/A N/A N/A	300 11.8 HIGH Triple washed DI < 1,200 particles 1,100 particles < 30 µg/g Non detectable level N/A N/A ✓	400 15.7 HIGH Triple washed < 1,200 particl 1,000 particl < 30 μg/g Non detectable N/A N/A ✔
EST-RP-CC005.4 50 11137-2:2015 :N 455-3:2015 :N 1149-1/2/3&5 PROTECTIO	CONTAMINATION NVR FTIR STERILITY ENDOTOXINS ESD	LENGTH (mm) LENGTH (inch) RTIES CONTAMINATION CONTROL LEVEL CONTAMINATION CONTROL PROCESS CONTAMINATION SPECIFICATION PARTICLES LEVEL CONTAMINATION TYPICAL PARTICLES VALUE NON-VOLATILE RESIDUE SILICONE, AMIDE, DOP LEVEL STERILITY ASSURANCE LEVEL ENDOTOXINS LEVEL ELECTROSTATIC PROPERTIES	300 11.8 BASIC Single washed DI < 3,000 particles 2,100 particles 2,100 particles < 30 µg/g Non detectable level N/A N/A N/A B [JKPT]	300 11.8 BASIC Single washed DI < 3,000 particles 2,300 particles 2,300 particles < 30 µg/g Non detectable level N/A N/A M/A B [KPT]	300 11.8 HIGH Triple washed DI < 1,200 particles 1,100 particles < 30 µg/g Non detectable level N/A N/A N/A ■ B [KPT]	400 15.7 HIGH Triple washed < 1,200 particl 1,000 particl < 30 µg/g Non detectable N/A N/A ✔ M/A ✔
EST-RP-CC005.4 50 11137-2:2015 N 455-3:2015 N 1149-1/2/3&5 PROTECTIO	CONTAMINATION NVR FTIR STERILITY ENDOTOXINS ESD N PROPER	LENGTH (mm) LENGTH (inch) RTIES CONTAMINATION CONTROL LEVEL CONTAMINATION CONTROL PROCESS CONTAMINATION SPECIFICATION PARTICLES LEVEL CONTAMINATION TYPICAL PARTICLES VALUE NON-VOLATILE RESIDUE SILICONE, AMIDE, DOP LEVEL SILICONE, AMIDE, DOP LEVEL SILICONE, AMIDE, DOP LEVEL ENDOTOXINS LEVEL ELECTROSTATIC PROPERTIES TIES TYPE	300 11.8 BASIC Single washed DI < 3,000 particles 2,100 particles 2,100 particles < 30 µg/g Non detectable level N/A N/A € B (JKPT) €	300 11.8 BASIC Single washed DI < 3,000 particles 2,300 particles 2,300 particles < 30 µg/g Non detectable level N/A N/A M/A M/A M/A	300 11.8 HIGH Triple washed DI < 1,200 particles 1,100 particles 1,100 particles < 30 µg/g Non detectable level N/A N/A N/A B [KPT] ✔	400 15.7 HIGH Triple washed < 1,200 particl 1,000 particl < 30 µg/g Non detectable N/A N/A N/A €
EST-RP-CC005.4 S0 11137-2:2015 N 455-3:2015 N 1149-1/2/3&5	CONTAMINATION NVR FTIR STERILITY ENDOTOXINS ESD N PROPER	LENGTH (mm) LENGTH (inch) RTIES CONTAMINATION CONTROL LEVEL CONTAMINATION CONTROL PROCESS CONTAMINATION SPECIFICATION PARTICLES LEVEL CONTAMINATION TYPICAL PARTICLES VALUE NON-VOLATILE RESIDUE SILICONE, AMIDE, DOP LEVEL SILICONE, AMIDE, DOP LEVEL STERILITY ASSURANCE LEVEL ENDOTOXINS LEVEL ENDOTOXINS LEVEL ELECTROSTATIC PROPERTIES TYPE PERMEATION (EN 16523-1:2015+A1:2018) PENETRATION (ISO 374-2:2019)	300 11.8 BASIC Single washed DI < 3,000 particles 2,100 particles 2,100 particles < 30 µg/g Non detectable level N/A N/A N/A S B [JKPT] ✓ C	300 11.8 BASIC Single washed DI < 3,000 particles 2,300 particles 2,300 particles < 30 µg/g Non detectable level N/A N/A N/A M/A M/A M/A M/A	300 11.8 HIGH Triple washed DI < 1,200 particles 1,100 particles 1,100 particles < 30 µg/g Non detectable level N/A N/A N/A B [KPT] ✓	400 15.7 HIGH Triple washed < 1,200 particl 1,000 particl < 30 μg/g Non detectable N/A N/A ✓ B (KPT) ✓
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EST-RP-CC005.4 50 11137-2:2015 50 455-3:2015 50 1149-1/2/3&5 <b>PROTECTIO</b> 50 374-1:2016+A1:2018	CONTAMINATION NVR FTIR STERILITY ENDOTOXINS ESD NPROPER CHEMICAL	LENGTH (mm) LENGTH (inch) RTIES CONTAMINATION CONTROL LEVEL CONTAMINATION CONTROL PROCESS CONTAMINATION SPECIFICATION PARTICLES LEVEL CONTAMINATION SPECIFICATION PARTICLES VALUE NON-VOLATILE RESIDUE SILICONE, AMIDE, DOP LEVEL STERILITY ASSURANCE LEVEL ENDOTOXINS LEVEL ELECTROSTATIC PROPERTIES TYPE PERMEATION (EN 16523-1:2015+A1:2018) PENETRATION (ISO 374-2:2019) DEGRADATION (ISO 374-2:2019) VIRUS (ISO 16604:2004 Procedure B)	300 11.8 BASIC Single washed DI < 3,000 particles 2,100 particles 2,100 particles < 30 µg/g Non detectable level N/A N/A N/A B [JKPT] B [JKPT] C	300 11.8 BASIC Single washed DI < 3,000 particles 2,300 particles 2,300 particles < 30 µg/g Non detectable level N/A N/A N/A B [KPT] ✓ ✓ ✓ ✓	300 11.8 HIGH Triple washed DI < 1,200 particles 1,100 particles < 30 µg/g Non detectable level N/A N/A N/A B [KPT] ✓ C C C C C C C C C C C C C C C C C C	400 15.7 HIGH Triple washed < 1,200 particle 1,000 particle < 30 μg/g Non detectable N/A N/A N/A

uniSHIELD™ technology

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

The comfort and protection of the workers are as important as process protection. Cleanroom gloves should protect the hands from the hazards for which they were selected, as well as contributing to the overall cleanliness of the cleanroom in sterile or non-sterile environments.



#### the right gloves is now an easy exercise!

Bright Latex 300 DI+	White Nitrile 300 DI++	Sterile ORANGE NITRILE™ 300 DI	Sterile Latex 300 DI	Sterile White Nitrile 330 DI+	Sterile Latex 400 DI+	Sterile White Nitrile 400 DI+	Sterile White Nitrile 600 DI+	ORANGE NITRILE™ 300 Sterile*
69 565X	69 885X	69 655X	69 555X	69 876 X	69 577X	69 877X	69 878X	67 635X
6/XS to 11/XXL	6/XS to 11/XXL	5.5 to 10.0	5.5 to 10.0	5.5 to 10.0	5.5 to 10.0	5.5 to 10.0	5.5 to 10.0	6/XS to 11/XXL
100 X 10 X 1	100 X 10 X 1							
		20 X 10	20 X 10	20 X 10	20 X 8	20 X 8	20 X 5	20 X 8
Category III	Category III	Category III	Category III	Category III	Category III	Category III	Category III	Category III
<ul> <li>✓</li> </ul>	<ul> <li>✓</li> </ul>	<ul> <li>✓</li> </ul>	<b>v</b>	<ul> <li>✓</li> </ul>	<b>v</b>	<ul> <li>✓</li> </ul>	<ul> <li>Image: A set of the set of the</li></ul>	<b>v</b>
V	V	<b>v</b>	<b>v</b>	<b>v</b>	<b>v</b>	<b>v</b>	<b>v</b>	v

								0
Natural Latex	Nitrile	Nitrile/Neoprene	Natural Latex	Nitrile	Natural Latex	Nitrile	Nitrile	Nitrile/Neoprene
Ambidextrous	Ambidextrous	Hand-specific	Hand-specific	Hand-specific	Hand-specific	Hand-specific	Hand-specific	Ambidextrous
Fully textured	Textured fingertips	Textured palm and fingers	Textured palm and fingers	Textured palm and fingers	Fully textured	Textured palm and fingers	Textured palm and fingers	Textured fingertips
Powder-free	Powder-free	Powder-free	Powder-free	Powder-free	Powder-free	Powder-free	Powder-free	Powder-free
Free of Thiurams and Thiazoles	Accelerator-free	Accelerator-free	Free of Thiurams and Thiazoles	Accelerator-free				
≤ 50 µg/g	Latex-free	Latex-free	≤ 50 µg/g	Latex-free	≤ 50 µg/g	Latex-free	Latex-free	Latex-free
uniSHIELD™	uniSHIELD™	uniSHIELD™	uniSHIELD™	uniSHIELD™	uniSHIELD™	uniSHIELD™	uniSHIELD™	twinSHIELD™
0.18	0.14	0.14	0.18	0.14	0.18	0.15	0.17	0.14
7.1	5.5	5.5	7.1	5.5	7.1	5.9	6.7	5.5
300	300	300	300	330	400	400	600	300
11.8	11.8	11.8	11.8	13.0	15.7	15.7	23.6	11.8

HIGH	EXTREME	BASIC	BASIC	HIGH	HIGH	HIGH	HIGH	BASIC
Triple washed DI	Multi washed DI	Single washed DI	Single washed DI	Triple washed DI	Triple washed DI	Triple washed DI	Triple washed DI	Single washed DI
< 1,200 particles	< 850 particles	< 3,000 particles	< 3,000 particles	< 1,200 particles	< 1,200 particles	< 1,200 particles	< 1,200 particles	< 3,000 particles
1,000 particles	600 particles	1,000 particles	1,100 particles	1,000 particles	1,100 particles	1,000 particles	1,000 particles	
< 30 µg/g	< 30 µg/g	< 30 µg/g	< 30 µg/g	< 30 µg/g	< 30 µg/g	< 30 µg/g	< 30 µg/g	×
Non detectable level	Non detectable level	Non detectable level	Non detectable level	Non detectable level	Non detectable level	Non detectable level	Non detectable level	×
N/A	N/A	10-6	10-6	10-6	10-6	10-6	10-6	10-6
N/A	N/A	< 20 EU/pair						
×	<ul> <li>Image: A set of the set of the</li></ul>	V	×	V	×	×	×	<ul> <li>Image: A set of the set of the</li></ul>

B (KPT)	B (KPT)	B (KPT)	B (KPT)	B (JKP)	B (KPT)	B (KPT)	B (KPT)	B (JKPT)
V	V	<b>v</b>	<ul> <li>Image: A set of the set of the</li></ul>	<b>v</b>	<ul> <li>Image: A set of the set of the</li></ul>	<ul> <li>Image: A set of the set of the</li></ul>	<b>v</b>	V
V	V	<b>v</b>	<ul> <li>Image: A set of the set of the</li></ul>	<b>v</b>	<ul> <li>Image: A set of the set of the</li></ul>	<ul> <li>Image: A set of the set of the</li></ul>	<b>v</b>	V
V	V	✓	✓	✓	<ul> <li>Image: A set of the set of the</li></ul>	<ul> <li>Image: A set of the set of the</li></ul>	✓	<ul> <li>✓</li> </ul>
<ul> <li>✓</li> </ul>	<b>v</b>	<b>v</b>	<ul> <li>Image: A set of the set of the</li></ul>	<b>v</b>	<ul> <li>Image: A set of the set of the</li></ul>	<ul> <li>Image: A set of the set of the</li></ul>	<b>v</b>	V
V	V	<b>v</b>	<ul> <li>Image: A set of the set of the</li></ul>	<b>v</b>	<ul> <li>Image: A set of the set of the</li></ul>	<ul> <li>Image: A set of the set of the</li></ul>	<b>v</b>	V
1.5 (Level 2)	1.5 (Level 2)	0.65 (Level 3)	0.65 (Level 3)	0.65 (Level 3)	0.65 (Level 3)	0.65 (Level 3)	0.65 (Level 3)	0.25 (Level 3)
×	x	V	X	V	X	v	X	V

protection because what is tested relates to the materials used, methods of manufacture, length and thickness of the glove. \*SHIELDskin™ brand.

#### 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: If there is a defect in one of the two layers, the second layer will keep your hand and your environment safe!

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#### SHIELDskin XTREME™ ORANGE NITRILE™ 300 DI

≣∳			0.	.17 mm/6.7 mil Textured	FORMULATION	COLOU	R	DES	IGN	ALLERGIES	CLEA	NLINESS
"- Standard length			0.14 mm 5.5 mil Smooth	Nitrile/Neoprene	Orange (outer) White (inner)	Ar	Ambidextrous Textured fingertips		Accelerator-fr Latex-free	ee in deio (< 3,00	e washed nized water 0 particles/ ≥ 0.5 µm)	
.8												
m/1			ſ		Size	6/XS	7/	s	8/M	9/L	10/XL	11/XXL
300 mm/11.8"-				0.10 mm 3 9 mil	Code	69 6451	69 6	452	69 645	3 69 6454	69 6455	69 6456
	3.9 m Beaded-cuf Powder-free Non-sterile		Beaded-cuff	100 gloves/PE bag	10 PE bags/poly bag 1 poly bag/cart					arton		
Po	owc	der-fre	e∘N	on-sterile								
/	_											



300 mm/11.8" - Standard length





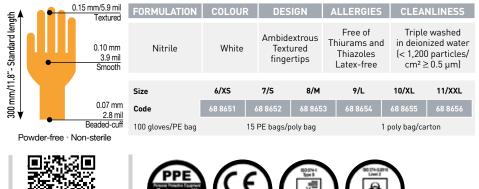
#### SHIELDskin XTREME™ White Nitrile 300 DI

0.15 mm/5.9 mil	FORMULATION	COLOUR	DES	IGN	ALLERGIES	CLEAI	NLINESS
0.13 mm 5.1 mil Smooth	Nitrile	White	Ambide Text finge	ured	Free of Thiurams and Thiazoles Latex-free	deioni: (< 3,000	washed in zed water ) particles/ 2 0.5 µm)
	Size	6/XS	7/S	8/M	9/L	10/XL	11/XXL
0.10 mm 3.9 mil	Code	69 8451	69 8452	69 845	3 69 8454	69 8455	69 8456
Beaded-cuff	100 gloves/PE bag		10 PE bags/p	oly bag	1	poly bag/ca	rton
Powder-free Non-sterile							





#### SHIELDskin XTREME™ Eco Nitrile 300 DI+



0598

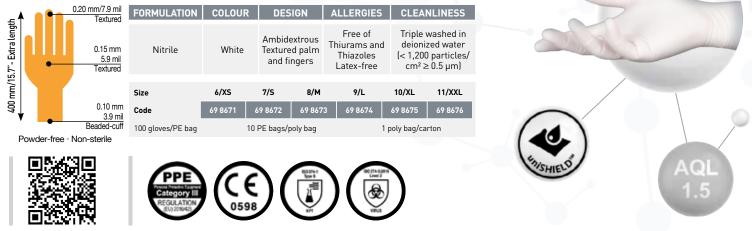


#### **CONTAMINATION CONTROL**

THE MORE THE GLOVE IS DI WATER WASHED, THE LOWER THE LEVEL OF PARTICLES

#### DI Basic contramination Control

#### SHIELDskin XTREME™ White Nitrile 400 DI+



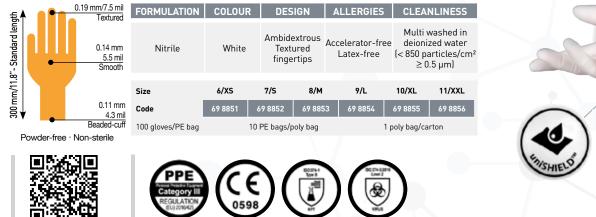


#### SHIELDskin XTREME™ Bright Latex 300 DI+





#### SHIELDskin XTREME™ White Nitrile 300 DI++



#### WWW.SHIELDSCIENTIFIC.COM

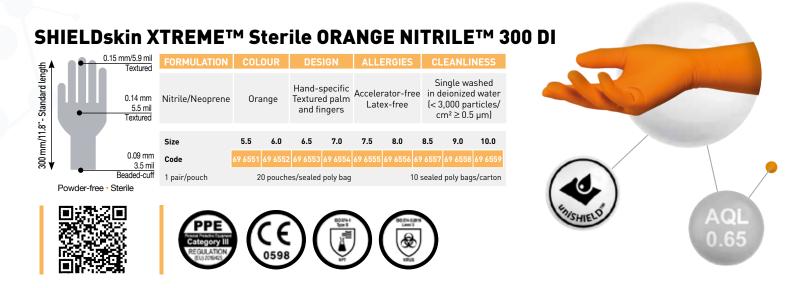
O



Depending on the procedure for sterile gowning, those engaged in aseptic work may double-glove with two pairs of sterile gloves. Disinfected bare hands may be used for putting on non-sterile garments such as bouffant caps and facemasks. However as soon as we start putting on sterile garments, then it is important that we are wearing sterile gloves.

SHIELDskin XTREME™ Sterile ORANGE NITRILE™ 300 DI (30cm) gloves are the ideal solution for the under-glove. Once we have finished putting on all the sterile garments, then we can don the second pair of sterile gloves. In this case the SHIELDskin XTREME™ Sterile White Nitrile 330 DI+ (33 cm) is the perfect partner, with the added benefit of extra length.

With this two-colour system, it is easy to detect punctures, pinpricks etc... on the white outer-glove thanks to the bright colour of the orange under-glove. It's also easy to replace the outer glove in the cleanroom and the presence of the sterile under-glove will minimize contamination of the product.





#### **DOUBLE DONNING** 2 COLOUR SYSTEM



#### **STEP 1:** FIRST PAIR UNPACKING

Select the appropriate gloves and size. Inspect the packages to check they are intact. Aseptically open peel pouch and deposit the wallet on a clean dry surface above waist height. Open wallet, handling only the outer flap of the wallet. Expose the gloves, whilst maintaining the sterile field.



#### **STEP 2:** FIRST PAIR DONNING

Grasp the folded cuff of the right glove with the left hand and insert fingers of right hand in right glove. Ensure that you touch only the inside of the glove. Pull the right glove onto the right hand by pulling the glove at the folded cuff. Ensure that the cuff remains folded. Slide fingers of the gloved right hand inside the folded cuff of the left glove. Insert the fingers of the left hand into the left glove. Pull the left glove on the hand, only touching the outside of glove with the gloved right hand. Unfold both right and left glove by handling only the outside of the glove with the gloved hand. Ensure that you pull at least 3 cm from the beaded cuff as pulling near the bead may lead to tearing.



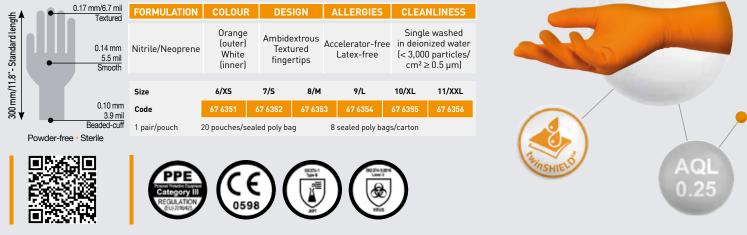
#### **STEP 3:** SECOND PAIR UNPACKING & DONNING

Prepare the second pair of gloves the same way as the first pair (see step 1. first pair unpacking). Grasp the folded cuff of the right glove with the left hand and insert fingers of right hand in right glove. Ensure that you only touch the inside of the glove. Pull the right glove onto the right hand by pulling the glove at the folded cuff. Ensure that the cuff remains folded. Slide fingers of the double gloved right hand inside the folded cuff of the left glove. Insert the fingers of the left hand into the left glove. Pull the left glove onto the left glove. Pull the left glove onto the left glove. Pull the left glove onto the glove with the gloved right hand. Unfold both right and left glove by handling only the outside of the glove with the gloved hand. Ensure that you pull at least 3 cm from the beaded cuff as pulling near the bead may lead to tearing.









**SHIELDskin XTREME™ DI** sterile latex and sterile nitrile gloves are developed specifically for sterile production in the pharmaceutical industry. These products provide appropriate process and product protection, along with personal protection for most aseptic environments.

**SHIELDskin XTREME™ DI+** sterile latex and sterile nitrile gloves have been specifically developed for the most critical environments in the pharmaceutical industry. A combination of different lengths and the highest level of barrier performance (as defined by AQL) ensure that these gloves offer maximum process and product protection as well as personal protection.

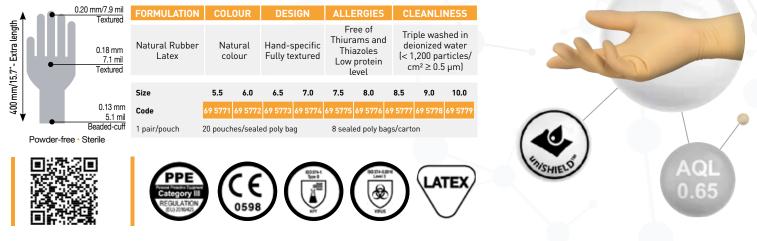


#### **BIO CONTAMINATION CONTROL**

PROTECT YOUR PROCESS, PRODUCT AND PERSONNEL IN ASEPTIC ENVIRONMENTS



#### SHIELDskin XTREME™ Sterile Latex 400 DI+



# AQL 0.65

#### SHIELDskin XTREME™ Sterile White Nitrile 400 DI+

_4		•	0.18 mm/7.1 mil Textured	FORMULATION	COL	OUR	DES	IGN	ALLE	RGIES	CL	CLEANLINESS	
5.7" - Extra length	15.7 <sup>-</sup> Extra leng		0.15 mm 5.9 mil Textured	Nitrile	White		Hand-specific Textured palm and fingers		Free of Thiurams and Thiazoles Latex-free		d de (< 1	Triple washed in deionized water (< 1,200 particles/ cm² ≥ 0.5 µm)	
400 mm/15.7" - I				Size	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0	10.0
400	,		0.10 mm .3 9 mil	Code	69 8771	69 8772	69 8773	69 8774	69 8775	69 8776	69 8777	69 8778	69 8779
•	▼ <u>3.9 mil</u> Beaded-cuff		Beaded-cuff	1 pair/pouch	2	0 pouch	es/sealed	l poly bag			8 sealed	poly bag	s/carton
	Pow	/der-fre	ee • Sterile										
Т		24	30			$\frown$		RORAL					

**(E**)

#### SHIELDskin XTREME™ Sterile White Nitrile 600 DI+

0598

	mm/7.9 mil Textured	FORMULATION	COLOUR	DESIGN	ALLERGIES	CLEANLINESS
	0.17 mm 6.7 mil Textured	Nitrile	White	Hand-specific Textured palm and fingers	Free of Thiurams and Thiazoles Latex-free	Triple washed in deionized water (< 1,200 particles/ cm² ≥ 0.5 μm)
		Size	5.5 6.0	6.5 7.0	7.5 8.0	8.5 9.0 10.0
	0.11 mm 4.3 mil	Code	69 8781 69 878:	2 69 8783 69 8784	69 8785 69 8786 69	9 8787 69 8788 69 8789
	Beaded-cuff	1 pair/pouch	20 pouch	nes/sealed poly bag	5 :	sealed poly bags/carton
Powder-free • St	erile					
				ROUTE A	00714.120	
	š	PPE	$(C \in$			i <b>n</b> –



# UNDERSTANDING DISPOSABLE GLOVE REGULATIONS AND STANDARDS

#### **REGULATIONS AND STANDARDS**

RELATING TO GLOVES SCOPE

ISO 21420:2020

General requirements for the design and manufacture of Personal Protective Equipment (PPE).

	GLOVE CATEGORY	RISK LEVEL	MARKING
	Category I	For minimal risks only.	Œ
Regulation (EU) 2016/425	Category II	For risks other than those listed in cat. I & III.	Œ
	Category III	For risks that may cause very serious consequences such as death or irreversible damage to health.	+ Notified Body

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, markings and information supplied by the manufacturer applicable to all protective gloves.

# CHEMICAL RISKSTANDARDS REFERENCESCOPEISO 374-1:2016+A1:2018Protective gloves against dangerous chemicals and micro-organisms.<br/>Part 1: Terminology and performance requirements for chemical risks.ISO 374-2:2019Protective gloves against dangerous chemicals and micro-organisms.<br/>Part 2: Determination of resistance to penetration.EN 16523-1:2015+A1:2018Determination of material resistance to permeation by chemicals.<br/>Part 1: Permeation by liquid chemical under conditions of continuous contact.ISO 374-4:2019Protective gloves against dangerous chemicals and micro-organisms.<br/>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).

50 374-1 Type A Type 8		MINIMUM	MINIMUM NUMBER OF	CODE LETTER	CHEMICAL	CAS NUMBER	CODE LETTER	CHEMICAL	CAS NUMBER
	CLASSIFICATION	PERFORMANCE	CHEMICALS	А	Methanol	67-56-1	J	n-Heptane	142-82-5
	CERSSITICATION	LEVEL REQUIRED	FROM THE	В	Acetone	67-64-1	Κ	Sodium hydroxide 40%	1310-73-2
AJKLADT KPT			18 LISTED	С	Acetonitrile	75-05-8	L	Suphuric acid 96%	7664-93-9
		Level 2	,	D	Dichloromethane	75-09-2	М	Nitric acid 65 %	7697-37-2
150 374-1:2016 Type C			0	E	Carbon disulphide	75-15-0	Ν	Acetic acid 99 %	64-19-7
	Turna D	Level 2	2	F	Toluene	108-88-3	0	Ammonium hydroxide 25%	1336-21-6
	Туре В	(min 30 minutes breackthrough)	ى 	G	Diethylamine	109-89-7	Ρ	Hydrogen proxide 30%	7722-84-1
	Type C	Level 1	1	Н	Tetrahydrofuran	109-99-9	S	Hydrofluoric acid 40%	7664-39-3
	iyhe C	(min 10 minutes breackthrough)	· · · · · · · · · · · · · · · · · · ·		Ethyl acetate	141-78-6	Т	Formaldehyde 37%	50-00-0



#### **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.

#### **CONTAMINATION RISK**

	STANDARDS REFERENCE	SCOPE
CLEANLINESS NVR - FTIR	IEST-RP-CC005.4	Procedures for testing and evaluating gloves and finger cots used in cleanrooms and other controlled environments.
STERILITY	ISO 11137-2:2015	Sterilization of health care products - Radiation. Part 2: Establishing the sterilization dose.
ENDOTOXINS	EN 455-3:2015	Medical gloves for single use Part 3: Requirement and testing for biological evaluation.
ESD	EN 1149-1/2/3&5	Protective clothing - Electrostatic properties. Part 1: Test method for measurement of surface resistivity. Part 2: Test method for measurement of the electrical resistance through a material (vertical resistance). Part 3: Test methods for measurement of charge decay. Part 5: Material performance and design requirements.
CYTOTOXIC DRUGS	ASTM D6978-05 (2019)	Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.

#### **MEDICAL USE**

STANDARDS REFERENCE	SCOPE	
<b>EN 455-1:2000</b> Medical gloves for single use – Part 1: Requirements and testing for freedom from hol		
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.	

# DI DI+ DI++ STERILE



#### SHIELD Scientific B.V.

Dr. Willem Dreeslaan 1 6721 ND BENNEKOM - THE NETHERLANDS Phone: + 31 (0) 317 700 202 Fax: + 31 (0) 318 503 742 Email: info@shieldscientific.com

WWW.SHIELDSCIENTIFIC.COM

