



SHIELD Scientific

compliance comfort protection

Cleanroom

Process & Personal Protection



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As being different is very much at the forefront of the founding values of SHIELD Scientific, it should not come as a surprise that the SHIELDskin Xtreme™ cleanroom glove range are branded very differently to many of our competitors. Whereas other glove manufacturers may wish to brand their gloves as ISO class 4 (Fed STD Class 10) or ISO Class 5 (Fed STD Class 100), we challenge this paradigm and would ask how classifications for airborne particulates relate to gloves. In reality there are no internationally recognised specification limits that would determine whether a cleanroom glove is ISO Class 4 (Fed STD Class 10) or ISO Class 5 (Fed STD Class 100) compatible. Accordingly it is left to users to decide what is suitable for their process. With this in mind, SHIELDskin Xtreme™ gloves are branded as follows:

| BRANDING | PROCESS | USER BENEFITS |
|------------------|---|---|
| DI | Single washed in deionised water | <ul style="list-style-type: none">• The most economical option• Typical particle levels < 3000 per cm² ≥ 0.5 µm |
| DI ⁺ | Triple washed in deionised water | <ul style="list-style-type: none">• The median brand option• Typical particle levels < 950 per cm² ≥ 0.5 µm |
| DI ⁺⁺ | Washed several times in deionised water | <ul style="list-style-type: none">• Premium offering based on extra processing• Typical particle levels < 650 per cm² ≥ 0.5 µm |

From this simple branding concept, the user can very clearly see that washing in deionised water provides the essential differentiation in terms of cleanliness properties

REGULATORY COMPLIANCE

Whilst process protection is typically the main concern, increasingly users are recognising that there is often an equal need for personal protection of employees from chemicals and biohazards. The responsibilities of the employer are outlined in the PPE at Work Directive 89/656/EEC which is enshrined in local legislation throughout the European Union. To address this need, all SHIELDskin Xtreme™ gloves are registered according to the PPE Directive 89/686/EEC.

EXCELLENCE IN ASEPTIC PROCESSING

For users of sterile glove, the SHIELDskin Xtreme™ Sterile Nitrile and Latex DI⁺ gloves offer the highest level of process and personal protection with an Acceptable Quality Level (AQL) for pinholes of 0,65. AQL is a crucial parameter for determining barrier properties. An AQL of 0,65 represents over 50% less defects than comparable sterile gloves on the market, providing superior process and personal protection from liquid penetration by micro-organisms and chemicals.



Detachable poster inside

Decontamination & packing processes

To ensure that the lowest contamination levels are maintained, SHIELDskin Xtreme™ gloves are manufactured under stringently controlled conditions. The gloves are processed with deionised water laundering cycles to achieve low levels of particles, extractable ions and non-volatile residues. Prior to packaging, the gloves are dried under HEPA filter driers. These critical steps are performed in controlled environments operating under cleanroom protocol to ensure that gloves are not exposed to environmental contaminants.



Certificate of conformance

As a guarantee of industry leading performance, SHIELD Scientific supplies a certificate of conformance (COC) on all SHIELDskin Xtreme™ DI* and DI** gloves. The COC provides lot specific data on critical elements such as particles and extractables, whilst for sterile gloves test data on endotoxin levels is also presented.



Certificate of irradiation

All sterile gloves are terminally sterilised by gamma irradiation to a Sterility Assurance Level (SAL) of 10^{-6} , in accordance with guidelines detailed in ANSI/AAMI/ EN ISO 11137:2006 "Sterilization of Healthcare Products – Radiation". Certificates of irradiation detailing the minimum and maximum dose of irradiation are available for every lot of sterile gloves.



Other test reports

SHIELD Scientific has been at the forefront of delivering extra value to customers by meeting unmet needs. To respond to the need for greater personal protection when handling cytotoxic drugs, we were amongst the first companies in Europe to promote testing of gloves against ASTM D6978 rather than the less stringent EN374-3. Likewise in response to the more tightly controlled conditions prevailing in IVF and stem cell research laboratories we offered embryo-toxicity testing for some of our gloves



Education

One of the founding objectives of SHIELD Scientific was to deliver educational programmes to the market. The frequency of requests for presentations on topical subjects such as glove legislation and glove-associated reactions highlight the popularity of these educational programmes. Specifically with reference to the cleanroom market, we have provided a poster on sterile donning techniques and developed a presentation that focuses on the handling of chemotherapy drugs.





SHIELDskin XTREME™

A Revolution in Glove Technology

P.P.E. Cat. III



DI+ STERILE GLOVES

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.

KEY FEATURES

- **Ultra low levels of particles and ionic residues** - tested according to IEST-RP-CC005.3 Test Methods to maximize safety of the process and product.
- **AQL 0,65** guarantees highest level of barrier protection from penetration of chemicals and micro-organisms in accordance with EN374-2:2003.
- **Registered as Category III (Complex Design) according to Council Directive 89/686/EEC** thereby assuring users of the highest level of personal protection.
- **Natural rubber latex versions are low in natural rubber latex proteins** with typical measurements $\leq 30 \mu\text{g/g}$.
- **Terminally sterilized by gamma irradiation to Sterility Assurance Level (SAL) of 10^{-6}** , in accordance with guidelines detailed in ANSI/AAMI/ EN ISO 11137:2006 "Sterilization of Healthcare Products – Radiation".
- **Low Endotoxin content** at $< 20 \text{ EU/pair}$ (EN455-3:2006) demonstrated by Limulus Amoebocyte Lysate (LAL) kinetic turbidimetric test.
- Manufactured in accordance with **ISO 9001:2000 and ISO 13485:2003**.
- **Hand specific design** gives optimum fit and comfort.

| | | | | | | | | | | |
|---|---------|---------|---------|---------|---------|---------|---------|---------|---|--|
| SHIELDskin Xtreme™ Sterile Latex 330 DI+ | | | | | | | | | 100% latex, powder free, hand specific, sterile, 33 cm, textured. | |
| Size | 6 | 6,5 | 7 | 7,5 | 8 | 8,5 | 9 | 10 | | |
| Code | 69 5762 | 69 5763 | 69 5764 | 69 5765 | 69 5766 | 69 5767 | 69 5768 | 69 5769 | | |

200 pairs/case = 20 pairs/bag x 10 bags/carton

| | | | | | | | | | | |
|---|---------|---------|---------|---------|---------|---------|---------|---------|--|--|
| SHIELDskin Xtreme™ Sterile Latex 400 DI+ | | | | | | | | | 100% latex, powder free, hand specific, sterile, 40 cm, textured palm. | |
| Size | 6 | 6,5 | 7 | 7,5 | 8 | 8,5 | 9 | 10 | | |
| Code | 69 5772 | 69 5773 | 69 5774 | 69 5775 | 69 5776 | 69 5777 | 69 5778 | 69 5779 | | |

160 pairs/case = 20 pairs/bag x 8 bags/carton

| | | | | | | | | | | |
|---|---------|---------|---------|---------|---------|---------|---------|---------|--|--|
| SHIELDskin Xtreme™ Sterile Latex 600 DI+ | | | | | | | | | 100% latex, powder free, hand specific, sterile, 60 cm, textured palm. | |
| Size | 6 | 6,5 | 7 | 7,5 | 8 | 8,5 | 9 | 10 | | |
| Code | 69 5782 | 69 5783 | 69 5784 | 69 5785 | 69 5786 | 69 5787 | 69 5788 | 69 5789 | | |

100 pairs/case = 20 pairs/bag x 5 bags/carton

| | | | | | | | | | | |
|---|---------|---------|---------|---------|---------|---------|---------|---------|---|--|
| SHIELDskin Xtreme™ Sterile White Nitrile 330 DI+ | | | | | | | | | 100% latex-free, powder free, hand specific, sterile, 33 cm, textured palm and fingers. | |
| Size | 6 | 6,5 | 7 | 7,5 | 8 | 8,5 | 9 | 10 | | |
| Code | 69 8762 | 69 8763 | 69 8764 | 69 8765 | 69 8766 | 69 8767 | 69 8768 | 69 8769 | | |

200 pairs/case = 20 pairs/bag x 10 bags/carton

P.P.E.: Personal Protective Equipment.
Size 5.5 is available on specific request only.

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**SHIELDskin Xtreme™
Sterile White Nitrile 400 DI+**

100% latex-free, powder free, hand specific, sterile, 40 cm, textured palm and fingers.

| | | | | | | | | |
|-------------|---------|---------|---------|---------|---------|---------|---------|---------|
| Size | 6 | 6,5 | 7 | 7,5 | 8 | 8,5 | 9 | 10 |
| Code | 69 8772 | 69 8773 | 69 8774 | 69 8775 | 69 8776 | 69 8777 | 69 8778 | 69 8779 |

160 pairs/case = 20 pairs/bag x 8 bags/carton



**SHIELDskin Xtreme™
Sterile White Nitrile 600 DI+**

100% latex-free, powder free, hand specific, sterile, 60 cm, textured palm and fingers.

| | | | | | | | | |
|-------------|---------|---------|---------|---------|---------|---------|---------|---------|
| Size | 6 | 6,5 | 7 | 7,5 | 8 | 8,5 | 9 | 10 |
| Code | 69 8782 | 69 8783 | 69 8784 | 69 8785 | 69 8786 | 69 8787 | 69 8788 | 69 8789 |

100 pairs/case = 10 pairs/bag x 10 bags/carton



P.P.E. Cat. III



DI STERILE GLOVES

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

KEY FEATURES

- **Low levels of particles and ionic residues** - tested according to IEST-RP-CC005.3 Test Methods to meet the needs of industries operating in clean environments.
- **AQL 0.65*** guarantees highest level of barrier protection from penetration of chemicals and micro-organisms in accordance with EN374-2:2003.
- **Registered as Category III (Complex Design) according to Council Directive 89/686/EEC**, thereby assuring users of the highest level of personal protection.
- **Natural rubber latex version is low in natural rubber latex proteins** typically ≤ 30 µg/g.
- **Terminally sterilized by gamma irradiation to Sterility Assurance Level (SAL) of 10⁻⁶**, in accordance with guidelines detailed in ANSI/AAMI/EN ISO 11137:2006 "Sterilization of Healthcare Products – Radiation"
- **Low endotoxin content** at < 20 EU/pair (EN455-3:2006) demonstrated by Limulus Amoebocyte Lysate (LAL) kinetic turbidimetric test.
- **Hand specific design** of SHIELDskin Xtreme™ Sterile Latex 300 DI gives optimum fit and comfort
- **Unique Skin Nitrile™ technology** of SHIELDskin Xtreme™ Sterile ORANGE NITRILE™ 300 DI results in a high level of elasticity and tactile sensitivity, not normally associated with an ambidextrous design.
- Manufactured in accordance with **ISO 9001:2000 and ISO 13485:2003**

SHIELDskin™ Sterile Latex 300

100% latex, powder free, hand specific, sterile, 30 cm, textured. AQL 1.5

| | | | | | | | | |
|-------------|---------|---------|---------|---------|---------|---------|---------|---------|
| Size | 6 | 6,5 | 7 | 7,5 | 8 | 8,5 | 9 | 10 |
| Code | 69 5552 | 69 5553 | 69 5554 | 69 5555 | 69 5556 | 69 5557 | 69 5558 | 69 5559 |

200 pairs/case = 20 pairs/bag x 10 bags/carton



**SHIELDskin™
Orange Nitrile™ 300 sterile**

100% nitrile, powder free, extra-long, ambidextrous, sterile, 30cm, textured fingertips. AQL 0.65

| | | | | | | | |
|-------------|---------|---------|---------|---------|---------|--------------|--------------|
| Size | XS / 6 | S / 7 | M / 8 | L / 9 | XL / 10 | Pairs/PE Bag | PE Bags/Case |
| Code | 67 6351 | 67 6352 | 67 6353 | 67 6354 | 67 6355 | 20 | 8 |

160 pairs/case = 20 pairs/bag x 8 bags/carton



P.P.E.: Personal Protective Equipment.
Size 5.5 is available on specific request only.
* Shieldskin™ Orange Nitrile 300 sterile only.



SHIELDskin XTREME™

A Revolution in Glove Technology

P.P.E. Cat. III



EN374-2:2003



LEVEL 2

EN374-1:2003



DI⁺⁺ NON STERILE GLOVES

SHIELDskin Xtreme™ 300 (30 cm) DI⁺⁺ are produced to offer extremely low levels of particles and ionic residues to cover the needs of especially the semiconductor industry. The medical device and pharmaceutical industries may also in the face of increasing regulatory pressure seek the same high level of cleanliness and SHIELDskin Xtreme™ 300 (30 cm) DI⁺⁺ could be the solution.

KEY FEATURES

- **Extremely low levels of particles and ionic residues** - tested according to IEST-RP-CC005.3 Test Methods in order to meet the most demanding needs of high end industries for product and process protection.
- **AQL 1,5** guarantees good barrier protection from penetration of chemicals and microorganisms in accordance with EN374-2:2003
- **Registered as Category III (Complex Design) according to Council Directive 89/686/EEC**, thereby assuring users of the highest level of personal protection.
- **Accelerator-Free** to minimize the risk of Allergic Contact Dermatitis
- Manufactured in accordance with **ISO 9001:2000 and ISO 13485:2003**

SHIELDskin Xtreme™
White Nitrile 300 DI⁺⁺

100% latex-free, powder-free,
ambidextrous, non sterile, 30 cm,
beaded cuff and textured fingertips.



| Size | XS / 6 | S / 7 | M / 8 | L / 9 | XL / 10 | XXL / 11 | Gloves/Bag | Bags/case |
|------|---------|---------|---------|---------|---------|----------|------------|-----------|
| Code | 69 8851 | 69 8852 | 69 8853 | 69 8854 | 69 8855 | 69 8856 | 100 | 10 |

P.P.E.: Personal Protective Equipment.
Size XXL/11 is available on specific request only.





SHIELDskin XTREME™

A Revolution in Glove Technology

P.P.E. Cat. III



EN374-2:2003



LEVEL 2

EN374-1:2003



DI+ NON STERILE GLOVES

SHIELDskin™ Xtreme™ 300 (30cm) DI+ gloves are manufactured for use in the cleanest environments in non sterile cleanrooms. Ultra low levels of particles and ionic residues make these products particularly suitable for the micro-electronic, medical device and pharmaceutical industries.

KEY FEATURES

- **Ultra low levels of particles and ionic residues** - tested according to IEST-RP-CC005.3 Test Methods to maximize safety of the process and product.
- **AQL 1,5** guarantees good barrier protection from penetration of chemicals and micro-organisms in accordance with EN374-2:2003.
- **Registered as Category III (Complex Design) according to Council Directive 89/686/EEC** thereby assuring users of the highest level of personal protection.
- **Natural rubber latex version is low in natural rubber latex proteins** - typically $\leq 30 \mu\text{g/g}$
- Manufactured in accordance with **ISO 9001:2000 and ISO 13485:2003.**

SHIELDskin Xtreme™ Bright Latex 300 DI+

100% latex, powder-free, ambidextrous, non sterile, 30 cm, beaded cuff and fully textured surface.

| Size | XS / 6 | S / 7 | M / 8 | L / 9 | XL / 10 | XXL / 11 | Gloves/Bag | Bags/case |
|------|---------|---------|---------|---------|---------|----------|------------|-----------|
| Code | 69 5651 | 69 5652 | 69 5653 | 69 5654 | 69 5655 | 69 5656 | 100 | 10 |



SHIELDskin Xtreme™ White Nitrile 300 DI+

100% latex-free, powder-free, ambidextrous, non sterile, 30 cm, beaded cuff and textured fingertips.

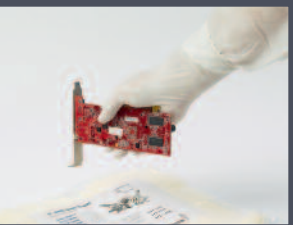
| Size | XS / 6 | S / 7 | M / 8 | L / 9 | XL / 10 | XXL / 11 | Gloves/Bag | Bags/case |
|------|---------|---------|---------|---------|---------|----------|------------|-----------|
| Code | 69 8651 | 69 8652 | 69 8653 | 69 8654 | 69 8655 | 69 8656 | 100 | 10 |



SHIELDskin Xtreme™ Eco Nitrile 300 DI+

100% latex-free, powder-free, ambidextrous, non sterile, 30 cm, beaded cuff and textured fingertips.

| Size | XS / 6 | S / 7 | M / 8 | L / 9 | XL / 10 | XXL / 11 | Gloves/Bag | Bags/case |
|------|---------|---------|---------|---------|---------|----------|------------|-----------|
| Code | 68 8651 | 68 8652 | 68 8653 | 68 8654 | 68 8655 | 68 8656 | 100 | 15 |



SHIELDskin Xtreme™ White Nitrile 400 DI+

100% latex-free, powder-free, ambidextrous, non sterile, 40 cm, beaded cuff and textured fingertips.

| Size | XS / 6 | S / 7 | M / 8 | L / 9 | XL / 10 | XXL / 11 | Gloves/Bag | Bags/case |
|------|---------|---------|---------|---------|---------|----------|------------|-----------|
| Code | 69 8671 | 69 8672 | 69 8673 | 69 8674 | 69 8675 | 69 8676 | 100 | 10 |



P.P.E.: Personal Protective Equipment.
Size XXL/11 is available on specific request only.





SHIELDskin XTREME™

A Revolution in Glove Technology

P.P.E. Cat. III



DI NON STERILE GLOVES

SHIELDskin™ Xtreme™ 300 (30cm) DI gloves offer low levels of particles and ions, by virtue of the gloves being rinsed in deionized water. This range of gloves represents the economic solution for non-sterile cleanrooms.

KEY FEATURES

- **Consistently reduced particle and ionic residues** - tested according to IEST-RP-CC005.3 Test Methods to maximize safety of the process and product.
- **AQL 1,5** guarantees good barrier protection from penetration of chemicals and micro-organisms in accordance with EN374-2:2003.
- **Registered as Category III (Complex Design) according to Council Directive 89/686/EEC** thereby assuring users of the highest level of personal protection.
- **Natural rubber latex version is low in natural rubber latex proteins** - typically $\leq 30 \mu\text{g/g}$.
- Manufactured in accordance with **ISO 9001:2000 and ISO 13485:2003**.

| | | | | | | | | | |
|--|---------|---------|---------|---------|---------|----------|--|-----------|--|
| SHIELDskin Xtreme™ White Nitrile 300 DI | | | | | | | 100% latex-free, powder-free, ambidextrous, non sterile, 30 cm, beaded cuff and textured fingertips. | | |
| Size | XS / 6 | S / 7 | M / 8 | L / 9 | XL / 10 | XXL / 11 | Gloves/Bag | Bags/case | |
| Code | 69 8451 | 69 8452 | 69 8453 | 69 8454 | 69 8455 | 69 8456 | 100 | 10 | |

| | | | | | | | | | |
|--|---------|---------|---------|---------|---------|----------|--|-----------|--|
| SHIELDskin Xtreme™ Eco Nitrile 300 DI | | | | | | | 100% latex-free, powder-free, ambidextrous, non sterile, 30 cm, beaded cuff and textured fingertips. | | |
| Size | XS / 6 | S / 7 | M / 8 | L / 9 | XL / 10 | XXL / 11 | Gloves/Bag | Bags/case | |
| Code | 68 8451 | 68 8452 | 68 8453 | 68 8454 | 68 8455 | 68 8456 | 100 | 15 | |

| | | | | | | | | | |
|--|---------|---------|---------|---------|---------|----------|--|-----------|--|
| SHIELDskin Xtreme™ orange Nitrile™ 300 DI | | | | | | | 100% latex-free, powder-free, ambidextrous, non sterile, 30 cm, beaded cuff and textured fingertips. | | |
| Size | XS / 6 | S / 7 | M / 8 | L / 9 | XL / 10 | XXL / 11 | Gloves/Bag | Bags/case | |
| Code | 69 6451 | 69 6452 | 69 6453 | 69 6454 | 69 6455 | 69 6456 | 100 | 10 | |

P.P.E.: Personal Protective Equipment.
Size XXL/11 is available on specific request only.

