

# EU Type Examination Certificate

This is to certify that:

SHIELD Scientific B.V.  
Costerweg 1-B, 6702 AA Wageningen,  
The Netherlands

Holds Certificate Number:

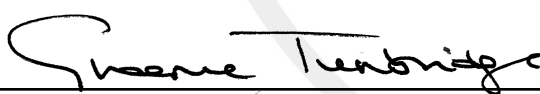
CE 811859

In respect of:

**Gloves for personal protection. Various models - see continuation sheet for details.**

on the basis that BSI carried out the relevant Type Examination procedures under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II

For and on behalf of BSI, a Notified  
Body for the above Regulation  
(Notified Body Number 2797):

  
Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

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# EU Type Examination Certificate

No. CE 811859

## Product Specification

Model:	SMARTLine™ Powder-free blue nitrile gloves, 240		
Product Codes	10 621 - XS/6;	10 622 - S/7;	
&Sizes:	10 623 - M/8;	10 624 - L/9;	
	10 625 - XL/10		
Classification:	Protective gloves for use against chemical and micro-organism hazards.		
PPE Category:	Category III		
Description:	Ambidextrous, single use, powder free, non-sterile, nitrile exam gloves with beaded cuff and textured finger, available in blue colour.		
Technical Specification	<p>Technical Specification to Annex II of the PPE Regulation (EU) 2016/425 based on the following standards:</p> <p>EN ISO 21420:2020 Protective gloves. General requirements and test methods.</p> <p>EN ISO 374-1:2016+A1:2018 Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for chemical risks.</p> <p>EN ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for micro-organisms risks.</p> <p>EN ISO 374-2:2019 Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to penetration. (Test Method)</p> <p>EN ISO 374-4:2019 Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to degradation by chemicals. (Test Method)</p> <p>EN 16523-1:2015+A1:2018 Determination of material resistance to permeation by chemicals. Permeation by potentially hazardous liquid chemicals under conditions of continuous contact. (Test Method)</p> <p>ISO 16604:2004 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. (Test Method)</p>		

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**Performance:**        **Resistance to penetration to EN ISO 374-2:2019**  
Pass

**Resistance to degradation to EN ISO 374-4:2019**  
Tested for the chemical listed below.

**Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018**  
**Type C Chemical protection** (Test method EN 16523-1:2015+A1:2018)

Chemical	Level
40% Sodium Hydroxide (K)	6

**Protection against micro-organism risks to EN ISO 374-5:2016**  
Bacteria and fungi (Test method EN ISO 374-2:2019)        Pass  
Viruses (Test Method ISO 16604:2004)        Pass

**General requirements for gloves to EN ISO 21420:2020**

<b>Dexterity:</b>	Level 5
<b>pH:</b>	Pass
<b>Size Range:</b>	XS, S, M, L, XL

(Continued)

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# EU Type Examination Certificate

No. CE 811859

**Product Specification**

**Model:** duoSHIELD™ ICE NITRILE™ 240

**Product Codes**      **65 5121 - XS/6;**                      **65 5122 - S/7;**

**&Sizes:**              **65 5123 - M/8;**                      **65 5124 - L/9;**

**65 5125 - XL/10**

**Classification:** Protective gloves for use against chemical and micro-organism hazards.

**PPE Category:** Category III

**Description:** Ambidextrous, single use, powder free, non-sterile, nitrile exam gloves with beaded cuff and textured fingertips, available in ice blue colour.

**Technical Specification**

Technical Specification to Annex II of the PPE Regulation (EU) 2016/425 based on the following standards:

EN ISO 21420:2020 Protective gloves. General requirements and test methods.

EN ISO 374-1:2016+A1:2018 Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for chemical risks.

EN ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for micro-organisms risks.

EN ISO 374-2:2019 Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to penetration. (Test Method)

EN ISO 374-4:2019 Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to degradation by chemicals. (Test Method)

EN 16523-1:2015+A1:2018 Determination of material resistance to permeation by chemicals. Permeation by potentially hazardous liquid chemicals under conditions of continuous contact. (Test Method)

ISO 16604:2004 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. (Test Method)

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# EU Type Examination Certificate

No. CE 811859

**Performance:**        **Resistance to penetration to EN ISO 374-2:2019**  
Pass

**Resistance to degradation to EN ISO 374-4:2019**  
Tested for all chemicals listed below.

**Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018**  
**Type B Chemical protection** (Test method EN 16523-1:2015+A1:2018)

Chemical	Level
40% Sodium Hydroxide (K)	6
30% Hydrogen Peroxide (P)	6
37% Formaldehyde (T)	5

**Protection against micro-organism risks to EN ISO 374-5:2016**

Bacteria and fungi (Test method EN ISO 374-2:2019)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

**General requirements for gloves to EN ISO 21420:2020**

<b>Dexterity:</b>	Level 5
<b>pH:</b>	Pass
<b>Size Range:</b>	XS, S, M, L, XL

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# EU Type Examination Certificate

No. CE 811859

**Product Specification**

**Model:** duoSHIELD™ PFT Nitrile 290

**Product Codes**      **65 8141 - XS/6;**                      **65 8142 - S/7;**  
**&Sizes:**              **65 8143 - M/8;**                      **65 8144 - L/9;**  
                             **65 8145 - XL/10**

**Classification:** Protective gloves for use against chemical and micro-organism hazards.

**PPE Category:** Category III

**Description:** Ambidextrous, single use, powder free, non-sterile, nitrile exam gloves with beaded cuff and textured fingertips, available in blue colour.

**Technical Specification**

Technical Specification to Annex II of the PPE Regulation (EU) 2016/425 based on the following standards:

EN ISO 21420:2020 Protective gloves. General requirements and test methods.

EN ISO 374-1:2016+A1:2018 Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for chemical risks.

EN ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for micro-organisms risks.

EN ISO 374-2:2019 Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to penetration. (Test Method)

EN ISO 374-4:2019 Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to degradation by chemicals. (Test Method)

EN 16523-1:2015+A1:2018 Determination of material resistance to permeation by chemicals. Permeation by potentially hazardous liquid chemicals under conditions of continuous contact. (Test Method)

ISO 16604:2004 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. (Test Method)

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**Performance:**        **Resistance to penetration to EN ISO 374-2:2019**  
Pass

**Resistance to degradation to EN ISO 374-4:2019**  
Tested for all chemicals listed below.

**Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018**  
**Type B Chemical protection** (Test method EN 16523-1:2015+A1:2018)

Chemical	Level
40% Sodium Hydroxide (K)	6
30% Hydrogen Peroxide (P)	6
37% Formaldehyde (T)	6

**Protection against micro-organism risks to EN ISO 374-5:2016**  
Bacteria and fungi (Test method EN ISO 374-2:2019)        Pass  
Viruses (Test Method ISO 16604:2004)        Pass

**General requirements for gloves to EN ISO 21420:2020**

**Dexterity:**                Level 5  
**pH:**                        Pass  
**Size Range:**            XS, S, M, L, XL

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# EU Type Examination Certificate

No. CE 811859

**Product Specification**

**Model:** duoSHIELD™ PFT Nitrile 240

**Product Codes**      **65 8121 - XS/6;**                      **65 8122 - S/7;**  
**&Sizes:**              **65 8123 - M/8;**                      **65 8124 - L/9;**  
                             **65 8125 - XL/10**

**Classification:** Protective gloves for use against chemical and micro-organism hazards.

**PPE Category:** Category III

**Description:** Ambidextrous, single use, powder free, non-sterile, nitrile exam gloves with beaded cuff and textured fingertips, available in blue colour.

**Technical Specification**

Technical Specification to Annex II of the PPE Regulation (EU) 2016/425 based on the following standards:

EN ISO 21420:2020 Protective gloves. General requirements and test methods.

EN ISO 374-1:2016+A1:2018 Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for chemical risks.

EN ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for micro-organisms risks.

EN ISO 374-2:2019 Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to penetration. (Test Method)

EN ISO 374-4:2019 Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to degradation by chemicals. (Test Method)

EN 16523-1:2015+A1:2018 Determination of material resistance to permeation by chemicals. Permeation by potentially hazardous liquid chemicals under conditions of continuous contact. (Test Method)

ISO 16604:2004 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. (Test Method)

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**Performance:**        **Resistance to penetration to EN ISO 374-2:2019**  
Pass

**Resistance to degradation to EN ISO 374-4:2019**  
Tested for all chemicals listed below.

**Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018**  
**Type B Chemical protection** (Test method EN 16523-1:2015+A1:2018)

Chemical	Level
40% Sodium Hydroxide (K)	6
30% Hydrogen Peroxide (P)	6
37% Formaldehyde (T)	6

**Protection against micro-organism risks to EN ISO 374-5:2016**  
Bacteria and fungi (Test method EN ISO 374-2:2019)        Pass  
Viruses (Test Method ISO 16604:2004)        Pass

**General requirements for gloves to EN ISO 21420:2020**

**Dexterity:**                Level 5  
**pH:**                        Pass  
**Size Range:**            XS, S, M, L, XL

(Continued)

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# EU Type Examination Certificate

No. CE 811859

## Product Specification

**Model:** SHIELDskin XTREME™ Eco Nitrile 300 DI+

<b>Product Codes</b>	<b>68 8651 - XS/6;</b>	<b>68 8652 - S/7;</b>
<b>&amp;Sizes:</b>	<b>68 8653 - M/8;</b>	<b>68 8654 - L/9;</b>
	<b>68 8655 - XL/10</b>	<b>68 8656 - XXL/11</b>

**Classification:** Protective gloves for use against chemical and micro-organism hazards.

**PPE Category:** Category III

**Description:** Ambidextrous, single use, powder free, non-sterile, nitrile cleanroom gloves with beaded cuff and textured fingertips, available in white colour.

**Technical Specification** Technical Specification to Annex II of the PPE Regulation (EU) 2016/425 based on the following standards:

EN ISO 21420:2020 Protective gloves. General requirements and test methods.

EN ISO 374-1:2016+A1:2018 Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for chemical risks.

EN ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for micro-organisms risks.

EN ISO 374-2:2019 Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to penetration. (Test Method)

EN ISO 374-4:2019 Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to degradation by chemicals. (Test Method)

EN 16523-1:2015+A1:2018 Determination of material resistance to permeation by chemicals. Permeation by potentially hazardous liquid chemicals under conditions of continuous contact. (Test Method)

ISO 16604:2004 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. (Test Method)

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BSI Group The Netherlands B.V., registered in the Netherlands under number 33264284, at John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands  
A member of BSI Group of Companies.

# EU Type Examination Certificate

No. CE 811859

**Performance:**        **Resistance to penetration to EN ISO 374-2:2019**  
Pass

**Resistance to degradation to EN ISO 374-4:2019**  
Tested for all chemicals listed below.

**Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018**  
**Type B Chemical protection** (Test method EN 16523-1:2015+A1:2018)

Chemical	Level
40% Sodium Hydroxide (K)	6
30% Hydrogen Peroxide (P)	6
37% Formaldehyde (T)	6

**Protection against micro-organism risks to EN ISO 374-5:2016**  
Bacteria and fungi (Test method EN ISO 374-2:2019)        Pass  
Viruses (Test Method ISO 16604:2004)        Pass

**General requirements for gloves to EN ISO 21420:2020**

**Dexterity:**                Level 5  
**pH:**                        Pass  
**Size Range:**            XS, S, M, L, XL, XXL

(Continued)

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# EU Type Examination Certificate

No. CE 811859

## Product Specification

**Model:** SHIELDskin XTREME™ White Nitrile 300 DI++

**Product Codes**      **69 8851 - XS/6;**                      **69 8852 - S/7;**  
**&Sizes:**              **69 8853 - M/8;**                      **69 8854 - L/9;**  
                             **69 8855 - XL/10**                      **69 8856 - XXL/11**

**Classification:** Protective gloves for use against chemical and micro-organism hazards.

**PPE Category:** Category III

**Description:** Ambidextrous, single use, powder free, non-sterile, nitrile cleanroom gloves with beaded cuff and textured fingertips, available in white colour.

**Technical Specification**

Technical Specification to Annex II of the PPE Regulation (EU) 2016/425 based on the following standards:

EN ISO 21420:2020 Protective gloves. General requirements and test methods.

EN ISO 374-1:2016+A1:2018 Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for chemical risks.

EN ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for micro-organisms risks.

EN ISO 374-2:2019 Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to penetration. (Test Method)

EN ISO 374-4:2019 Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to degradation by chemicals. (Test Method)

EN 16523-1:2015+A1:2018 Determination of material resistance to permeation by chemicals. Permeation by potentially hazardous liquid chemicals under conditions of continuous contact. (Test Method)

ISO 16604:2004 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. (Test Method)

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**Performance:**        **Resistance to penetration to EN ISO 374-2:2019**  
Pass

**Resistance to degradation to EN ISO 374-4:2019**  
Tested for all chemicals listed below.

**Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018**  
**Type B Chemical protection** (Test method EN 16523-1:2015+A1:2018)

Chemical	Level
40% Sodium Hydroxide (K)	6
30% Hydrogen Peroxide (P)	6
37% Formaldehyde (T)	6

**Protection against micro-organism risks to EN ISO 374-5:2016**  
Bacteria and fungi (Test method EN ISO 374-2:2019)        Pass  
Viruses (Test Method ISO 16604:2004)        Pass

**General requirements for gloves to EN ISO 21420:2020**

**Dexterity:**                Level 5  
**pH:**                        Pass  
**Size Range:**            XS, S, M, L, XL, XXL

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# EU Type Examination Certificate

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## Product Specification

**Model:** SHIELDskin XTREME™ White Nitrile 400 DI+

**Product Codes**      **69 8671 - XS/6;**                      **69 8672 - S/7;**  
**&Sizes:**              **69 8673 - M/8;**                      **69 8674 - L/9;**  
                             **69 8675 - XL/10**                      **69 8676 - XXL/11**

**Classification:** Protective gloves for use against chemical and micro-organism hazards.

**PPE Category:** Category III

**Description:** Ambidextrous, single use, powder free, non-sterile, nitrile cleanroom gloves with beaded cuff and textured palm and cuff, available in white colour.

**Technical Specification**

Technical Specification to Annex II of the PPE Regulation (EU) 2016/425 based on the following standards:

EN ISO 21420:2020 Protective gloves. General requirements and test methods.

EN ISO 374-1:2016+A1:2018 Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for chemical risks.

EN ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for micro-organisms risks.

EN ISO 374-2:2019 Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to penetration. (Test Method)

EN ISO 374-4:2019 Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to degradation by chemicals. (Test Method)

EN 16523-1:2015+A1:2018 Determination of material resistance to permeation by chemicals. Permeation by potentially hazardous liquid chemicals under conditions of continuous contact. (Test Method)

ISO 16604:2004 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. (Test Method)

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**Performance:**        **Resistance to penetration to EN ISO 374-2:2019**  
Pass

**Resistance to degradation to EN ISO 374-4:2019**  
Tested for all chemicals listed below.

**Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018**  
**Type B Chemical protection** (Test method EN 16523-1:2015+A1:2018)

Chemical	Level
40% Sodium Hydroxide (K)	6
30% Hydrogen Peroxide (P)	6
37% Formaldehyde (T)	6

**Protection against micro-organism risks to EN ISO 374-5:2016**  
Bacteria and fungi (Test method EN ISO 374-2:2019)        Pass  
Viruses (Test Method ISO 16604:2004)        Pass

**General requirements for gloves to EN ISO 21420:2020**

**Dexterity:**                Level 5  
**pH:**                        Pass  
**Size Range:**            XS, S, M, L, XL, XXL

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## Product Specification

<b>Model:</b>	SHIELDskin XTREME™ Sterile White Nitrile 400 DI+
<b>Product Codes</b>	<b>69 8771 - 5.5; 69 8772 - 6; 69 8773 - 6.5; 69 8774 - 7;</b>
<b>&amp;Sizes:</b>	<b>69 8775 - 7.5; 69 8776 - 8; 69 8777 - 8.5; 69 8778 - 9;</b> <b>69 8779 – 10</b>
<b>Classification:</b>	Protective gloves for use against chemical and micro-organism hazards.
<b>PPE Category:</b>	Category III
<b>Description:</b>	Hand-specific, single use, powder free, sterile, nitrile cleanroom gloves with beaded cuff and textured palm and fingers, available in white colour.
<b>Technical Specification</b>	<p>Technical Specification to Annex II of the PPE Regulation (EU) 2016/425 based on the following standards:</p> <p>EN ISO 21420:2020 Protective gloves. General requirements and test methods.</p> <p>EN ISO 374-1:2016+A1:2018 Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for chemical risks.</p> <p>EN ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for micro-organisms risks.</p> <p>EN ISO 374-2:2019 Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to penetration. (Test Method)</p> <p>EN ISO 374-4:2019 Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to degradation by chemicals. (Test Method)</p> <p>EN 16523-1:2015+A1:2018 Determination of material resistance to permeation by chemicals. Permeation by potentially hazardous liquid chemicals under conditions of continuous contact. (Test Method)</p> <p>ISO 16604:2004 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. (Test Method)</p>

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**Performance:**        **Resistance to penetration to EN ISO 374-2:2019**  
Pass

**Resistance to degradation to EN ISO 374-4:2019**  
Tested for all chemicals listed below.

**Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018**  
**Type B Chemical protection** (Test method EN 16523-1:2015+A1:2018)

Chemical	Level
40% Sodium Hydroxide (K)	6
30% Hydrogen Peroxide (P)	6
37% Formaldehyde (T)	6

**Protection against micro-organism risks to EN ISO 374-5:2016**  
Bacteria and fungi (Test method EN ISO 374-2:2019)        Pass  
Viruses (Test Method ISO 16604:2004)        Pass

**General requirements for gloves to EN ISO 21420:2020**

**Dexterity:**                Level 5  
**pH:**                        Pass  
**Size Range:**            5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 10

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# EU Type Examination Certificate

No. CE 811859

## Product Specification

**Model:** SHIELDskin XTREME™ Sterile ORANGE NITRILE™ 300 DI

**Product Codes** **69 6551 - 5.5; 69 6552 - 6; 69 6553 - 6.5; 69 6554 - 7;**

**&Sizes:** **69 6555 - 7.5; 69 6556 - 8; 69 6557 - 8.5; 69 6558 - 9;**  
**69 6559 – 10**

**Classification:** Protective gloves for use against chemical and micro-organism hazards.

**PPE Category:** Category III

**Description:** Hand-specific, single use, powder free, sterile, nitrile/neoprene cleanroom gloves with beaded cuff and textured palm and fingers, available in orange colour.

**Technical Specification**

Technical Specification to Annex II of the PPE Regulation (EU) 2016/425 based on the following standards:

EN ISO 21420:2020 Protective gloves. General requirements and test methods.

EN ISO 374-1:2016+A1:2018 Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for chemical risks.

EN ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for micro-organisms risks.

EN ISO 374-2:2019 Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to penetration. (Test Method)

EN ISO 374-4:2019 Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to degradation by chemicals. (Test Method)

EN 16523-1:2015+A1:2018 Determination of material resistance to permeation by chemicals. Permeation by potentially hazardous liquid chemicals under conditions of continuous contact. (Test Method)

ISO 16604:2004 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. (Test Method)

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# EU Type Examination Certificate

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**Performance:**        **Resistance to penetration to EN ISO 374-2:2019**  
Pass

**Resistance to degradation to EN ISO 374-4:2019**  
Tested for all chemicals listed below.

**Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018**  
**Type B Chemical protection** (Test method EN 16523-1:2015+A1:2018)

Chemical	Level
40% Sodium Hydroxide (K)	6
30% Hydrogen Peroxide (P)	6
37% Formaldehyde (T)	6

**Protection against micro-organism risks to EN ISO 374-5:2016**  
Bacteria and fungi (Test method EN ISO 374-2:2019)        Pass  
Viruses (Test Method ISO 16604:2004)        Pass

**General requirements for gloves to EN ISO 21420:2020**

**Dexterity:**                Level 5  
**pH:**                        Pass  
**Size Range:**            5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 10

(Continued)

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No. CE 811859

## Product Specification

<b>Model:</b>	SHIELDskin XTREME™ Sterile White Nitrile 600 DI+
<b>Product Codes</b>	<b>69 8781 - 5.5; 69 8782 - 6; 69 8783 - 6.5; 69 8784 - 7;</b>
<b>&amp;Sizes:</b>	<b>69 8785 - 7.5; 69 8786 - 8; 69 8787 - 8.5; 69 8788 - 9;</b> <b>69 8789 – 10</b>
<b>Classification:</b>	Protective gloves for use against chemical and micro-organism hazards.
<b>PPE Category:</b>	Category III
<b>Description:</b>	Hand-specific, single use, powder free, sterile, nitrile cleanroom gloves with beaded cuff and textured palm and fingers, available in white colour.
<b>Technical Specification</b>	<p>Technical Specification to Annex II of the PPE Regulation (EU) 2016/425 based on the following standards:</p> <p>EN ISO 21420:2020 Protective gloves. General requirements and test methods.</p> <p>EN ISO 374-1:2016+A1:2018 Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for chemical risks.</p> <p>EN ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for micro-organisms risks.</p> <p>EN ISO 374-2:2019 Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to penetration. (Test Method)</p> <p>EN ISO 374-4:2019 Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to degradation by chemicals. (Test Method)</p> <p>EN 16523-1:2015+A1:2018 Determination of material resistance to permeation by chemicals. Permeation by potentially hazardous liquid chemicals under conditions of continuous contact. (Test Method)</p> <p>ISO 16604:2004 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. (Test Method)</p>

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**Performance:**        **Resistance to penetration to EN ISO 374-2:2019**  
Pass

**Resistance to degradation to EN ISO 374-4:2019**  
Tested for all chemicals listed below.

**Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018**  
**Type B Chemical protection** (Test method EN 16523-1:2015+A1:2018)

Chemical	Level
40% Sodium Hydroxide (K)	6
30% Hydrogen Peroxide (P)	6
37% Formaldehyde (T)	6

**Protection against micro-organism risks to EN ISO 374-5:2016**  
Bacteria and fungi (Test method EN ISO 374-2:2019)        Pass  
Viruses (Test Method ISO 16604:2004)        Pass

**General requirements for gloves to EN ISO 21420:2020**

**Dexterity:**                Level 5  
**pH:**                        Pass  
**Size Range:**            5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 10

(Continued)

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To check its validity telephone +31 20 3460780. An electronic certificate can be authenticated [online](#).

# EU Type Examination Certificate

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## Product Specification

Model:	SMARTLine™ Sterile Light Nitrile 300 DI	
Product Codes	20 631 - XS/6;	20 632 - S/7;
&Sizes:	20 633 - M/8;	20 634 - L/9;
	20 635 - XL/10;	20 636 - XXL/11
Classification:	Protective gloves for use against chemical and micro-organism hazards.	
PPE Category:	Category III	
Description:	Ambidextrous, single use, powder free, sterile, nitrile cleanroom gloves with beaded cuff and textured fingertips, available in white colour.	
Technical Specification	<p>Technical Specification to Annex II of the PPE Regulation (EU) 2016/425 based on the following standards:</p> <p>EN ISO 21420:2020 Protective gloves. General requirements and test methods.</p> <p>EN ISO 374-1:2016+A1:2018 Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for chemical risks.</p> <p>EN ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for micro-organisms risks.</p> <p>EN ISO 374-2:2019 Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to penetration. (Test Method)</p> <p>EN ISO 374-4:2019 Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to degradation by chemicals. (Test Method)</p> <p>EN 16523-1:2015+A1:2018 Determination of material resistance to permeation by chemicals. Permeation by potentially hazardous liquid chemicals under conditions of continuous contact. (Test Method)</p> <p>ISO 16604:2004 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. (Test Method)</p>	

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**Performance:**        **Resistance to penetration to EN ISO 374-2:2019**  
Pass

**Resistance to degradation to EN ISO 374-4:2019**  
Tested for all chemicals listed below.

**Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018**  
**Type B Chemical protection** (Test method EN 16523-1:2015+A1:2018)

Chemical	Level
40% Sodium Hydroxide (K)	6
30% Hydrogen Peroxide (P)	6
37% Formaldehyde (T)	6

**Protection against micro-organism risks to EN ISO 374-5:2016**

Bacteria and fungi (Test method EN ISO 374-2:2019)	Pass
Viruses (Test Method ISO 16604:2004)	Pass

**General requirements for gloves to EN ISO 21420:2020**

<b>Dexterity:</b>	Level 5
<b>pH:</b>	Pass
<b>Size Range:</b>	XS, S, M, L, XL, XXL

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# EU Type Examination Certificate

No. CE 811859

## Certificate Administration Details

Technical File Reference: TF#04\_Single Tone Series rev.07

## Certificate Amendment Record:

Issue Date	Comments
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December 2024	First issue.
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Internal BSI Project  
Number

2797:24:30207452

## Certificate validity

The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspect of the overall process utilised in the manufacture of the product, failure to do so could invalidate the Certificate in respect of product manufactured following the introduction of such changes.

The validity of the Certificate for the products is also dependent on the maintenance of the EU Conformity to Type based on Internal Production Control plus supervised product checks at random intervals, Annex VII (Module C2) as referenced on BSI issued Certificate CE 769779.

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