

EU Type Examination Certificate

This is to certify that:

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

Holds Certificate Number:

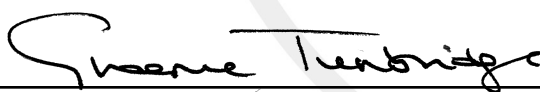
CE 811858

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

First Issued: 2024-12-19

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EU Type Examination Certificate

No. CE 811858

Product Specification

Model:	ecoSHIELD™ Eco Nitrile PF 250	
Product Codes	62 5121 - XS/6;	62 5122 - S/7;
&Sizes:	62 5123 - M/8;	62 5124 - L/9;
	62 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 gloves with beaded cuff and textured fingertips, available in green 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
30% Hydrogen Peroxide (P)	6
37% Formaldehyde (T)	5
n-Heptane (J)	2

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 811858

Product Specification

Model: SHIELDskin™ ORANGE NITRILE™ 260

Product Codes **67 6231 - XS/6;** **67 6232 - S/7;**
&Sizes: **67 6233 - M/8;** **67 6234 - L/9;**
 67 6235 - 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/neoprene gloves with beaded cuff and textured fingertips, 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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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
n-Heptane (J)	2

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 811858

Product Specification

Model: SHIELDskin™ ORANGE NITRILE™ 300

Product Codes	67 6251 - XS/6;	67 6252 - S/7;
&Sizes:	67 6253 - M/8;	67 6254 - L/9;
	67 6255 - XL/10	67 6256 - 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/neoprene gloves with beaded cuff and textured fingertips, 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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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
n-Heptane (J)	2

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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Product Specification

Model: SHIELDskin™ ORANGE NITRILE™ 300 Sterile

Product Codes	67 6351 - XS/6;	67 6352 - S/7;
&Sizes:	67 6353 - M/8;	67 6354 - L/9;
	67 6355 - XL/10	67 6356 - 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/neoprene gloves with beaded cuff and textured fingertips, 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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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
n-Heptane (J)	2

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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Product Specification

Model: SHIELDskin™ XTREME™ ORANGE NITRILE™ 300 DI

Product Codes	69 6451 - XS/6;	69 6452 - S/7;
&Sizes:	69 6453 - M/8;	69 6454 - L/9;
	69 6455 - XL/10	69 6456 - 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/neoprene cleanroom gloves with beaded cuff and textured fingertips, 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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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
n-Heptane (J)	2

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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Certificate Administration Details

Technical File Reference: TF#03_twinSHIELD Series rev.06

Certificate Amendment Record:

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

2797:24:30207449

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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