

EU Type Examination Certificate

This is to certify that:

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

Holds Certificate Number:

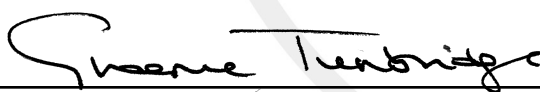
CE 811857

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: 2024-12-18

Latest Issue: 2024-12-18

Effective Date: 2024-12-18

Expiry Date: 2029-12-17



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EU Type Examination Certificate

No. CE 811857

Product Specification

Model:	SHIELDskin XTREME™ Sterile Latex 400 DI+
Product Codes	69 5771 - 5.5; 69 5772 - 6; 69 5773 - 6.5; 69 5774 - 7;
&Sizes:	69 5775 - 7.5; 69 5776 - 8; 69 5777 - 8.5; 69 5778 - 9; 69 5779 – 10
Classification:	Protective gloves for use against chemical and micro-organism hazards.
PPE Category:	Category III
Description:	Hand-specific, single use, powder free, sterile, rubber latex cleanroom gloves with beaded cuff and textured palm and fingers, available in natural 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	
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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EU Type Examination Certificate

No. CE 811857

Product Specification

Model: SHIELDskin XTREME™ Sterile Latex 300 DI

Product Codes **69 5551 - 5.5; 69 5552 - 6; 69 5553 - 6.5; 69 5554 - 7;**

&Sizes: **69 5555 - 7.5; 69 5556 - 8; 69 5557 - 8.5; 69 5558 - 9;**
69 5559 – 10

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

PPE Category: Category III

Description: Hand-specific, single use, powder free, sterile, natural rubber latex cleanroom gloves with beaded cuff and textured palm and fingers, available in natural 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:	5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 10

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

EU Type Examination Certificate

No. CE 811857

Product Specification

Model: duoSHIELD™ LPS Latex 240

Product Codes **65 1121 - XS/6;** **65 1122 - S/7;**
&Sizes: **65 1123 - M/8;** **65 1124 - L/9;**
 65 1125 - XL/10

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

PPE Category: Category III

Description: Ambidextrous, single use, powdered, non-sterile, natural rubber latex exam gloves with beaded cuff, available in natural 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)	4
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 811857

Product Specification

Model: duoSHIELD™ PFT Latex 240

Product Codes **65 4121 - XS/6;** **65 4122 - S/7;**
&Sizes: **65 4123 - M/8;** **65 4124 - L/9;**
 65 4125 - 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, textured natural rubber latex exam gloves with beaded cuff, available in natural 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)	5
30% Hydrogen Peroxide (P)	6
37% Formaldehyde (T)	4

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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No. CE 811857

Product Specification

Model: ecoSHIELD™ Eco Latex PF 250

Product Codes **62 3131 - XS/6;** **62 3132 - S/7;**
&Sizes: **62 3133 - M/8;** **62 3134 - L/9;**
 62 3135 - 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, natural rubber latex gloves with beaded cuff, available in natural 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 811857

Product Specification

Model: SHIELDskin XTREME™ Bright Latex 300 DI+

Product Codes **69 5651 - XS/6;** **69 5652 - S/7;**
&Sizes: **69 5653 - M/8;** **69 5654 - L/9;**
 69 5655 - XL/10 **69 5656 - 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, textured natural rubber latex gloves with beaded cuff, available in natural 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

(Continued)

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EU Type Examination Certificate

No. CE 811857

Product Specification

Model: SMARTLine™ Sterile Latex 400 DI

Product Codes	20 451 - XS/6;	20 452 - S/7;
&Sizes:	20 453 - M/8;	20 454 - L/9;
	20 455 - XL/10	20 456 - XXL/11

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

PPE Category: Category III

Description: Ambidextrous, single use, powder free, sterile, textured natural rubber latex cleanroom gloves with beaded cuff, available in natural 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

No. CE 811857

Product Specification

Model: SMARTLine™ Sterile Latex 600 DI

Product Codes	20 471 - XS/6;	20 472 - S/7;
&Sizes:	20 473 - M/8;	20 474 - L/9;
	20 475 - XL/10	20 476 - XXL/11

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

PPE Category: Category III

Description: Ambidextrous, single use, powder free, sterile, textured natural rubber latex cleanroom gloves with beaded cuff, available in natural 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.

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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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Certificate Administration Details

Technical File Reference: TF#02_NRL Series rev.7

Certificate Amendment Record:

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

2797:24:30206447

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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