

# EU Type Examination Certificate

This is to certify that:

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

Holds Certificate Number:

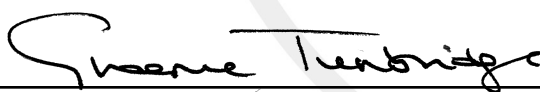
CE 794345

In respect of:

**Gloves for personal protection. Models: SHIELDskin XTREME™ White Nitrile 300 DI, SHIELDskin XTREME™ Sterile White Nitrile 330 DI+.**

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: 2023-09-05

Latest Issue: 2024-12-13

Effective Date: 2024-12-13

Expiry Date: 2028-09-04



Page: 1 of 6

# EU Type Examination Certificate

No. CE 794345

## Product Specification

|                         |  |         |
|-------------------------|--|---------|
| Model:                  | SHIELDskin XTREME™ White Nitrile 300 DI  |         |
| Product Codes:          | 69 8451  | 69 8454 |
|                         | 69 8452  | 69 8455 |
|                         | 69 8453  | 69 8456 |
| 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) |         |

First Issued: 2023-09-05  
Latest Issue: 2024-12-13

Effective Date: 2024-12-13  
Expiry Date: 2028-09-04

# EU Type Examination Certificate

No. CE 794345

**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.

| <b>Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018</b>   |              |
|---|--------------|
| <b>Type B Chemical protection</b> (Test method EN 16523-1:2015+A1:2018) |              |
| <b>Chemical</b>   | <b>Level</b> |
| 40% Sodium Hydroxide (K)  | 6            |
| 30% Hydrogen Peroxide (P)   | 6            |
| 37% Formaldehyde (T)  | 6            |

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

| <b>General requirements for gloves to EN ISO 21420:2020</b> |                                    |
|---|------------------------------------|
| <b>Dexterity:</b>   | Level 5                            |
| <b>pH:</b>  | Pass                               |
| <b>Size Range:</b>  | 6/XS, 7/S, 8/M, 9/L, 10/XL, 11/XXL |

(Continued)

First Issued: 2023-09-05  
Latest Issue: 2024-12-13

Effective Date: 2024-12-13  
Expiry Date: 2028-09-04

# EU Type Examination Certificate

No. CE 794345

## Product Specification

**Model:** SHIELDskin XTREME™ Sterile White Nitrile 330 DI+

|                       |                |                |
|-----------------------|----------------|----------------|
| <b>Product Codes:</b> | <b>69 8761</b> | <b>69 8766</b> |
|                       | <b>69 8762</b> | <b>69 8767</b> |
|                       | <b>69 8763</b> | <b>69 8768</b> |
|                       | <b>69 8764</b> | <b>69 8769</b> |
|                       | <b>69 8765</b> |                |

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

**PPE Category:** Category III

**Description:** Hand-specific, single use, powder free, sterile, nitrile cleanroom gloves with beaded cuff and textured palm and fingers, 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)

First Issued: 2023-09-05

Effective Date: 2024-12-13

Latest Issue: 2024-12-13

Expiry Date: 2028-09-04

Page: 4 of 6

This certificate has been issued by and remains the property of BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands and should be returned immediately upon request.  
To check its validity telephone +31 20 3460780. An electronic certificate can be authenticated [online](#).

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 794345

**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) | 2     |
| 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> | 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 10 |

First Issued: 2023-09-05  
Latest Issue: 2024-12-13

Effective Date: 2024-12-13  
Expiry Date: 2028-09-04

# EU Type Examination Certificate

No. CE 794345

## Certificate Administration Details

Technical File Reference: TF01-02\_69 876X\_69 845X.rev.5

## Certificate Amendment Record:

| Issue Date     | Comments   | Internal BSI Project Number |
|----------------|--|-----------------------------|
| September 2023 | First issue.   | 2797:23:3967233             |
| December 2024  | Update of the certificate holder address, change the chemical 30% Hydrogen Peroxide (P) permeation resistance from level 6 to level 2 for model SHIELDskin XTREME™ Sterile White Nitrile 330 DI+ and other administrative changes. | 2797:24:30269990            |

## 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.

First Issued: 2023-09-05

Latest Issue: 2024-12-13

Effective Date: 2024-12-13

Expiry Date: 2028-09-04

Page: 6 of 6

This certificate has been issued by and remains the property of BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands and should be returned immediately upon request.  
To check its validity telephone +31 20 3460780. An electronic certificate can be authenticated [online](#).

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.