

Conformity to Type based on Internal Production Control plus supervised product checks at random intervals

This is to certify that:

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

Holds Certificate Number:

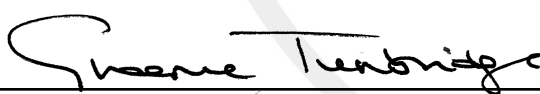
CE 769779

In respect of:

For the manufacture of gloves to the standards specified on the continuation sheet

on the basis that BSI carried out the supervised production checks at random intervals under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex VII (Module C2)

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: 2022-11-09

Latest Issue: 2024-12-13

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Page: 1 of 5

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PPE Module B Certificate holding location:

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

Product Specification

The gloves models covered by the scope of this Module C2 certificate conform to the following Technical Specification to Annex II of the PPE Regulation (EU) 2016/425 based on the following standards:

Manufacturing Sites:

See Technical File TF01-02_69 876X_69 845X for details.

Product Description

Model: SHIELDskin XTREME™ White Nitrile 300 DI;
Model: SHIELDskin XTREME™ Sterile White Nitrile 330 DI+

Technical Specification

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-organism risks.

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Manufacturing Sites: See Technical File TF#02_NRL Series for details.

Product Description Model: SHIELDskin XTREME™ Sterile Latex 400 DI+;
Model: SHIELDskin XTREME™ Sterile Latex 300 DI;
Model: duoSHIELD™ LPS Latex 240;
Model: duoSHIELD™ PFT Latex 240;
Model: ecoSHIELD™ Eco Latex PF 250;
Model: SHIELDskin XTREME™ Bright Latex 300 DI+;
Model: SMARTLine™ Sterile Latex 400 DI;
Model: SMARTLine™ Sterile Latex 600 DI

Technical Specification

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-organism risks.

Manufacturing Sites: See Technical File TF#03_twinSHIELD Series for details.

Product Description Model: ecoSHIELD™ Eco Nitrile PF 250;
Model: SHIELDskin™ ORANGE NITRILE™ 260;
Model: SHIELDskin™ ORANGE NITRILE™ 300;
Model: SHIELDskin™ ORANGE NITRILE™ 300 Sterile;
Model: SHIELDskin™ XTREME™ ORANGE NITRILE™ 300 DI

Technical Specification

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-organism risks.

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Manufacturing Sites: See Technical File TF#04_Single Tone Series for details.

Product Description Model: SMARTLine™ Powder-free blue nitrile gloves, 240;
Model: duoSHIELD™ ICE NITRILE™ 240;
Model: duoSHIELD™ PFT Nitrile 290;
Model: duoSHIELD™ PFT Nitrile 240;
Model: SHIELDskin XTREME™ Eco Nitrile 300 DI+;
Model: SHIELDskin XTREME™ White Nitrile 300 DI++;
Model: SHIELDskin XTREME™ White Nitrile 400 DI+;
Model: SHIELDskin XTREME™ Sterile White Nitrile 400 DI+;
Model: SHIELDskin XTREME™ Sterile ORANGE NITRILE™ 300 DI;
Model: SHIELDskin XTREME™ Sterile White Nitrile 600 DI+;
Model: SMARTLine™ Sterile Light Nitrile 300 DI

Technical Specification

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-organism risks.

Manufacturing Sites: See Technical File TF#05_NEO NITRILE for details.

Product Description Model: SHIELDskin CHEM™ NEO NITRILE™ 300

Technical Specification

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-organism risks.

EN 388:2016+A1:2018 Protective gloves against mechanical risks

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Certificate Administration Details

Certificate Amendment Record and BSI internal Review relating to this Certificate:

Issue Date	Comments	BSI Project Number
November 2022	First issue.	2797:22:3662885
May 2023	Update to standard EN ISO 21420:2020 and addition of model reference.	2797:23:3817484
August 2023	Addition of manufacturing site (details are hidden).	2797:23:3930650
December 2024	Update of the certificate holder address, addition of new models and manufacturing sites (details are hidden) and removal of the first manufacturing site and models from it.	2797:24:30207507

Certificate validity

The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspects of the overall process used in the manufacture of the products. Failure to do so could invalidate the Certificate in respect of product manufactured after the introduction of such changes.

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