

UKCA Type Examination Certificate

This is to certify that:

Medline International France SAS
5 Rue Charles Lindbergh
Châteaubriant
44110
France

Holds Certificate Number:

UKCA 746712

In respect of:

**Model Mediguard Special Nitrile Disposable Examination Gloves
To EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018 and EN ISO 374-5:2016**

On the basis that BSI carried out the relevant Type Examination procedures under the requirements with the Regulation 2016/425 on Personal Protective Equipment, as amended to apply in GB (PPE) Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II.

For and on behalf of BSI, an Approved
Body for the above Regulation
(Approved Body Number 0086):



Shahm Barhom, Group Product Certification Director

First Issued: 2022-05-10

Latest Issue: 2023-03-15

Effective Date: 2023-03-15

Expiry Date: 2027-05-10



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Product Specification

Model: Mediguard Special Nitrile Examination Gloves.

Classification: Protective gloves for use against dangerous chemicals and micro-organisms.

Description: Non sterile, single use, five fingered, powder free Nitrile gloves. The gloves have a tight cuff seal and blue coloured.

Size range: Extra Small, Small, Medium, Large and Extra Large.

Product Codes: MGSNXS, MGSNS, MGSNM, MGSNL, MGSNXL

PPE Category: Category III - Complex.

Technical Specification: Type Examination for all PPE models listed in this certificate is conducted to Annex II of the Regulation 2016/425 on personal protective equipment, as amended to apply in GB, and based on the following European Standards:

EN ISO 21420:2020 – Protective gloves. General requirements.

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

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

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

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

EN 16523-1:2015+A1:2018 – Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to permeation by chemicals.

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.

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Performance

EN ISO 21420:2020- General requirements:

Characteristic	Performance
Length and Fit	Pass
Dexterity	Level 5
pH value	Pass
PAH	Pass

EN ISO 374-2:2019 – Protection against penetration by micro-organisms

Pass

EN ISO 374-4:2019 – Resistance to degradation

Tested for all chemicals listed below.

EN ISO 374-1:2016+A1:2018 – Resistance to chemical permeation

Type B chemical protection (Test method EN 16523-1:2015+A1:2018)

Code Letter	Chemical	Permeation Level
K	40% Sodium Hydroxide	4
P	30% Hydrogen Peroxide	2
T	37% Formaldehyde	3

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

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

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Certificate Administration Details

Technical File Reference: 'Tech File no 24, Non-sterile Examination gloves'.

Certificate Administration Record and BSI internal Technical File Review reference

Issue date	Comments	BSI Project Ref.
April 2022	First issue to the Regulation 2016/425 on personal protective equipment, as amended to apply in GB.	0086:22:3408437
March 2023	Extension to scope – change of claim from Type C to Type B at two INTCO locations. Removal of KINGFA, Hongray, YTY suppliers. Standard updated to EN ISO 21420:2020.	0086:23:3852526

Note: The Certificate holder is responsible for keeping the Approved Body advised of changes to any aspect of the overall process used in the manufacture of the product.

Monitoring of manufactured PPE

The validity of the Certificate for the products is also dependent on the maintenance of the 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 UKCA 746687.

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