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Technical Data Sheet

Mediguard Special Nitrile

Disposable Non-sterile Nitrile – Powder free glove

Reference & Size

MGSNXS	MGSNS	MGSNM	MGSNL	MGSNXL	Fits either hand
XS	S	M	L	XL	

Primary Material

Latex-free
Power-free nitrile

Color

Blue

Surface

Fingertip textured

Cuff Design

Beaded cuff

Chemical additive (accelerators)

Carbamate

Powder Content (per EN455-3)

Powder content: 0.58 milligrams per glove

Average Thickness

Finger Tip	0.09 mm
Palm	0.06 mm
Cuff	0.06 mm

Packaging

200 gloves per box, 10 boxes per case (XL – 180 gloves per box)
Box dimensions: 245mm L * 125mm W * 74mm H
Case dimensions: 382mm L * 257mm W * 255mm H

Revision: 3
Document Number: EU1-00004-F-00025 Document Title: FINT 441 - Technical sheet

EU Type Examination Certificate

This is to certify that:

Medline International France SAS
5 Rue Charles Lindbergh
Châteaubriant
44110
France

Holds Certificate Number:

CE 739234

In respect of:

Disposable Examination Gloves to EN 420:2003+A1:2009, EN ISO 374-1:2016+A1:2018 and EN ISO 374-5:2016
Model: Mediguard Special Nitrile Examination Gloves

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):

Drs. Dave Hagenaaars, Managing Director

First Issued: 2021-05-07

Latest Issue: 2021-05-07

Effective Date: 2021-05-07

Expiry Date: 2026-05-07

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EU Type Examination Certificate

No. CE 739234

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.
Applicable Standards:	<p>The following Harmonized European Standards:</p> <p>EN 420:2003+A1:2009 - Protective gloves. General requirements.</p> <p>EN ISO 374-1:2016+A1:2018 - Protective gloves against chemicals and micro-organisms – Part 1 Terminology and performance requirements.</p> <p>EN ISO 374-2:2019 - Protective gloves against dangerous chemicals and micro-organisms – Part 2 Determination of resistance to penetration.</p> <p>EN ISO 374-4:2019 – Protective gloves against chemicals and micro-organisms. Determination of resistance to degradation by chemicals.</p> <p>EN ISO 374-5:2016 – Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for micro-organism risks.</p> <p>EN 16523-1:2015+A1:2018 - Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to permeation by chemicals.</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.</p>

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EU Type Examination Certificate

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Performance

EN 420:2003+A1:2009 - General requirements:

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

EN ISO 374-2:2019 – Protection against penetration by micro-organisms. Determination of resistance to penetration.

Characteristic	Performance
Water Leak	Pass

EN ISO 374-4:2019 – Resistance to degradation

Tested for all chemicals listed below.

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

Code Letter	Chemical	Permeation Level
K	40% Sodium Hydroxide	4

ISO 16604:2004 Resistance to penetration by blood-borne pathogens

Pass

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No. CE 739234

Certificate Administration Details

Technical File Reference: 'Tech File no 24, Non-sterile Examination gloves, Rev 13'

Certificate Administration Record and BSI internal Technical File Review reference

Issue date	Comments	BSI Project Ref.
May 2021	Initial issue	2797:21:3324899

Note: The Certificate holder is responsible for keeping the Notified 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 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 653430.

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Mechanical & Hardgoods Laboratory

TEST REPORT

Report No. : HL50134/2019

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Date : MAY 24, 2019

The following merchandise was submitted and identified by the applicant as:

Product Description: Disposable Nitrile Glove (blue beaded ambidextrous)

Style/Item No.: NPF2005-XL

We have tested the submitted sample(s) as requested and the following results were obtained:

Test Requested: Viral Penetration Test (Refer to ASTM F 1671-2013)

Test Method & Result: ---See following sheet(s)---

Date of Receipt : MAY 06, 2019

Testing Period : MAY 06, 2019 ~ MAY 24, 2019

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TEST REPORT

Report No. : HL50134/2019

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Test Method & Result:

Test Items		Results				Test Method
		Step			Assay	
		1	2	3	(PFU/mL)	
Penetration of Phi-X174 Bacteriophage	Control (+)	None Seen	Seen	--	--	ASTM F1671-2013
	Control (-)	None Seen	None Seen	None Seen	<1	
	Specimen 1	None Seen	None Seen	None Seen	<1	
	Specimen 2	None Seen	None Seen	None Seen	<1	
	Specimen 3	None Seen	None Seen	None Seen	<1	

Note:

1. Testing procedure of Penetration of Phi-X174 Bacteriophage:

Step 1: Observe for 5 min at 0 psi.

Step 2: Slowly increase the pressure to 2.0 psi at the rate of no more than 0.5 psi/s, keep the pressure at 2.0 psi, observe for 1 min.

Step 3: Slowly decrease the pressure to 0 psi at the rate of no more than 0.5 psi/s, observe for 54 min.

2. 1 psi = 6.895 kPa

3. PFU: Plaque Forming Unit

4. 2.0 E+2 is equal to 200, 1.3 E+4 is equal to 13000, etc.

5. A retaining screen is used.

6. Sample description is given by the client: Disposable Nitrile Glove.

Remark:

1. The test report is the test results issued by the testing institution as requested by the consignor, it shall not determine the legitimacy of the product.

2. This testing was performed by Taiwan Textile Research Institute.

TEST REPORT

Report No. : HL50134/2019

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– Picture(s) –



Photo A: Appearance of the sample(s)

---End of Report---