EU Declaration of Conformity

Manufacturer:	Medicare Products Ltd
Manufacturer's Address:	Unit B, Dolphin Way, Purfleet, Essex, RM19 1NZ
Product Brand:	Nitrex Ultra Sensitive
Product Description:	Blue nitrile powder free disposable glove
Product Code:	GN92
PPE Category:	Category III
Medical Device Category:	Class I

It is declared that the above product:

- is in conformity with the provisions of Regulation (EU) 2016/425 on personal protective equipment and with National Standards transposing harmonised standards EN 374-1:2016, EN 374-5:2016, and EN 420:2003+A1:2009.

- is identical to the personal protective equipment which is the subject of EU Type-Examination Certificate number 2777/10015-03/E13-01, issued by SATRA Technology Europe Limited, Bracetown Business Park, Clonee, Dublin, D15 YN2P, Republic of Ireland (Notified Body number 2777), according to Annex V (Module B) of Regulation (EU) 2016/425.

- is subject to the conformity assessment procedure Module C2 set out in Annex VII of Regulation (EU) 2016/425, under the surveillance of the notified body SATRA Technology Europe Limited, Bracetown Business Park, Clonee, Dublin, D15 YN2P, Republic of Ireland (Notified Body number 2777).

- is in conformity with the provisions of Council Directive 93/42/EEC on medical devices and with National Standards transposing harmonised standards EN 455-1:2000, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, and is self-certified as a Class 1 non-sterile medical device (according to Annex IX rule 5).

This EU declaration of conformity is issued under the sole responsibility of the manufacturer, Medicare Products Ltd.

Signed for and on behalf of:	Medicare Products Ltd
Place of issue:	Purfleet
Name and role:	Gary Sira, Director
Signature:	
Expiry Date:	21st April 2023

NITREX

medicare PRODUCTS

GN92
NITREX Ultra Sensitive

- Latex-Free
- Powder-Free
- Micro-Textured Fingers
- Ultimate Tactile Sensitivity
- Good Chemical Resistance

NITREX Ultra Sensitive examination gloves are manufactured from a high quality nitrile formulation resulting in a strong performing glove with a high level of tactile sensitivity.

The advanced thin film technology utilised in the manufacture process results in a glove, which is suitable for a wide range of tasks in multiple environments.

Specification

Glove details	Specification
Material	Nitrile
Length	Min. 240mm
Protein Level	Contains no latex proteins
Surface	Micro-textured fingers
Shape	Ambidextrous
Colour	Blue
Sterilisation	Non sterile
Shelf Life	Min. 3 Years

Physical Properties

Glove details	Properties
Force at Break (Newtons)	>6
Freedom from Holes	AQL 1.5
Length (mm)	Min. 240
Cuff Thickness (mm)	0.04
Palm Thickness (mm)	0.05
Finger Thickness (mm)	0.06

AQL (Acceptable Quality Level) refers to the maximum number of defective products that could be considered acceptable during the random sampling of an inspection, in this case freedom from holes in gloves. The lower the number, the fewer the holes and the higher the quality of gloves.

Sizing

Size	Palm width
Extra Small	75 ± 5mm
Small	85 ± 5mm
Medium	95 ± 5mm
Large	106 ± 5mm
Extra Large	116 ± 5mm

Quantities

Code	Box Qty	Case Qty
GN92E	200 Gloves	10 Boxes
GN92S	200 Gloves	10 Boxes
GN92M	200 Gloves	10 Boxes
GN92L	200 Gloves	10 Boxes
GN92X	200 Gloves	10 Boxes

Re-order Codes

Size	MPC	NHS Code
Extra Small	GN92E	FTE2895
Small	GN92S	FTE2894
Medium	GN92M	FTE2893
Large	GN92L	FTE2892
Extra Large	GN92X	FTE2891

Quality standards: Manufactured in a facility holding ISO 9001 and ISO 13485.

Product standards:
Medical Device Directive (MDD)
This product is classified as a Class I Medical Device and complies with European Standards EN 455-1:2000, EN 455-2:2015, EN 455-3:2015 and EN 455-4:2009.

PPE EU Type-Examination
This product is classed as Category III Personal Protective Equipment (PPE) according to the PPE Regulation (EU) 2016/425.

Storage: Store in a cool, dry place away from sources of heat or direct sunlight and shielded from ozone and UV light.

Disposal: Dispose of gloves as clinical waste. Collection case and transit case can be recycled as paper or disposed of as clinical waste. Please follow your organisation's policies for disposal.

Shelf life: Minimum three (3) years from date of manufacture.

Country of origin: Malaysia

Notice: This product is free from natural rubber latex and is suitable for use in latex-free environments. Components used in glove manufacturing may cause allergic reactions in some users. If allergic reactions occur, stop use and seek medical advice immediately.

CE

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AQL 1.5

LATEX
latex free

Find out more at www.medicareproducts.com

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MPL/GN92/SPEC
REV2/8-02-18

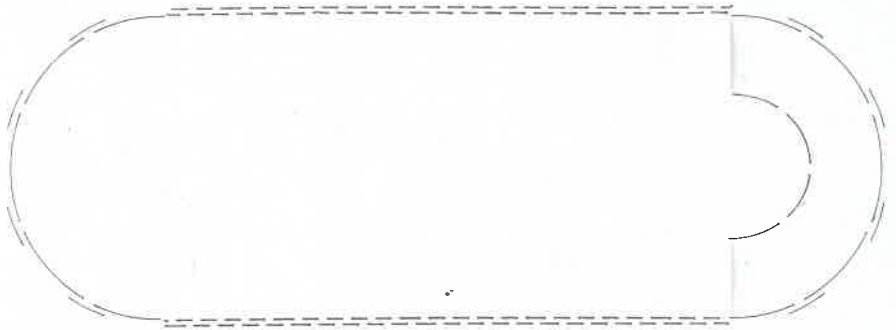
medisafe

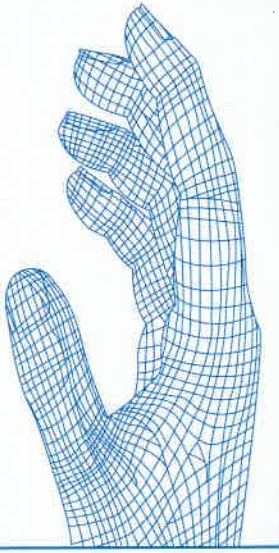
NITREX

Ultra Sensitive

Ultra Sensitive

Superior Comfort





NEW GENERATION POWDER FREE NITRILE EXAMINATION GLOVES

Manufactured in accordance with Quality Management System ISO 13485 & ISO 9001

Designed and Produced to meet the applicable requirements of EN455 (Parts 1, 2, 3 and 4) / EN ISO 374 (Parts 1 & 5)

200 LARGE (8-9)
MEDICAL GLOVES

Medical Device Regulation (MDR)

This product is classified under Class I Medical Device per Rule 1 and Rule 5 of Annex VIII, meets the provision of Medical Device Regulation (EU) 2017/745.
Complies with European Standards EN 455-1:2000, EN 455-2:2015, EN 455-3:2015, & EN 455-4:2009.

PPE EU Type-Examination

This product is classed as Category III Personal Protective Equipment (PPE) according to PPE Regulation (EU) 2016/425 and has been shown to comply with this Regulation through the Harmonised European Standards EN420:2003+A1:2009, EN ISO 374-1:2016/Amd.1:2018(E), EN ISO 374-1:2016 and EN ISO 374-5:2016.
Notified Body responsible for (i) certification and Module B compliance & (ii) internal production control plus supervised product checks at random intervals (Module C2) is SATRA TECHNOLOGY EUROPE LIMITED, 2777, Bracetown Business Park, Clonee, Dublin 15, D15 YN2P, Ireland.
The EU Declaration of Conformity is accessible at www.medicareproducts.com

ISO 374-5:2016 ISO 374-1/Type B

VIRUS KPT

Food Handling

This product complies with the rules of the Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food

Gloves for Special Applications (EN 420:2003+A1:2009, Clause 5.1.3)

These gloves are designed primarily for medical use. Therefore, the glove length is specified in accordance with the requirements of EN455 and is below the EN420 requirements of total minimum glove length, and the product is deemed as 'Fit for Special Purpose'

Marking

a) Micro Organism Hazards Pictogram (shown below): EN ISO 374-5:2016 Protection against Bacteria, Fungi and Viruses. No penetration of bacteriophage detected through the test specimen.

ISO 374-5:2016

b) Chemical Hazards Pictogram: EN ISO 374-1:2016; Additional information on chemical resistance obtainable from manufacturer.
EN ISO 374-1:2016 permeation levels are based on breakthrough times as follows:

Performance Level	1	2	3	4	5	6
Minimum breakthrough time (mins)	>10	>30	>60	>120	>240	>480

This product complies with Type B requirements and the following pictogram is used with reference to clause 6.3 of EN ISO 374-1.

ISO 374-1/Type B

Performance and Limitation of Use

a) This product has been tested in accordance with EN ISO 374-5:2016.
Protection against bacteria and fungi - pass
Protection against virus - pass

b) Gloves had been tested in accordance with EN ISO 374-1: 2016 resistance to permeation by chemicals and achieved the performance levels shown in Table A.
i) This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals.
ii) The chemical resistance has been assessed under laboratory conditions from samples taken from the palm only and relates only to the chemical tested. It can be different if the chemical used in a mixture.
iii) It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on temperature, abrasion and degradation.
iv) When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation is an important factor to consider in selection of chemical resistant gloves.
v) Before usage, inspect the gloves for any defect or imperfections.

c) This product had been tested in accordance with BS EN 374-4:2013 and achieved the degradation results shown in Table A.
i) EN 374-4:2013 Degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemicals.

d) This product provides protection against Bacteria, Fungi and Virus. The gloves had been tested in accordance with ISO 16604:2014 to meet the requirements of BS EN ISO 374-5:2016 for resistance to penetration by blood-borne pathogens-test method using Phi-X174 bacteriophage.
i) The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.

Table A	EN ISO 374-1: 2016	BS EN 374-4:2013
Chemical	Level	Mean Degradation/%
*4% Chlorhexidine Digluconate	6	19.0
40% Sodium Hydroxide (K)	6	-42.9
10-13% Sodium Hypochlorite	6	14.7
50% Sulphuric Acid	6	-20.5
10% Acetic acid	4	66.7
5% Ethidium Bromide	6	3.4
37% Formaldehyde (T)	3	5.0
65% Nitric Acid (M)	0	97.6
50% Glutaraldehyde	6	27.4
0.1% Phenol	6	33.8
30% Hydrogen peroxide (P)	2	22.8
1.5% Methanol in water	6	21.9
70% Isopropanol	0	62.2
35% Ethanol	0	38.8
99% Acetic acid (N)	0	93.9
25% Ammonium Hydroxide (0)	1	-52.0
3% Povidone Iodine	6	33.7
10% Sodium Percarbonate	6	15.4

*The minimum observable permeation rate was 7ug/cm2/min.

e) The gloves were found to meet with the REACH annex XVII requirements for Polycyclic Aromatic Hydrocarbons (PAHs).

f) Components used in glove manufacturing may cause allergic reactions in some users. If allergic reactions occur, seek medical advice immediately.

Product Instruction for Use

a) Usage - For Single Use only. If re-used, the risk of contamination and infection increases due to Improper cleaning processes; and increased risk of holes and tear during re-use due to weakening of gloves by cleaning processes.

b) Sizing - Select the right size glove for your hand.

c) Donning - Hold glove by the bead with one hand. Align the glove thumb with your other hand thumb and slide your hand into the glove, one finger into each glove finger. Pull by the glove palm to a get a good fit. Don the other glove by the same procedure.

d) Inspection - Punctures or tears may occur after donning. Inspect each glove after donning, and immediately discontinue use if found damaged.

e) Doffing - Hold glove bead and pull toward the finger until the glove come off.

f) Disposal - Properly disposal of all used gloves. Follow your Institution's policies for disposal.

Handling and Storage

Store in a cool and dry place. Opened boxes should be kept away from fluorescent light and sunlight. Gloves are packed in dispenser which is suitable for transport. Keep the gloves in the box when not in use.