Paseo de la Castellana 141, plantas 18 y 19, Cuzco IV
28046-Madrid
T. 91.048.29.47

USER INFORMATION

Product code: GD20B – GD20W – GD20N

Product Name: **GD20B** POWDER FREE NITRYLE BLUE EXAMINATION GLOVES, NON-STERILE
GD20W POWDER FREE NITRYLE WHITE EXAMINATION GLOVES, NON-STERILE
GD20N POWDER FREE NITRYLE EXAMINATION GLOVES, NON-STERILE

Available sizes: S (GD20BB – GD20WB – GD20NB),
M (GD20BC – GD20WC – GD20NC),
L (GD20BD – GD20WD – GD20ND),
XL (GD20BE – GD20WE – GD20NE).

Manufacturer: SANTEX INTERNACIONAL SL
Address: PASEO DE LA CASTELLANA 141, PLANTAS 18 Y 19, CUZCO IV 28046-MADRID (SPAIN).

1) Medical Device Regulation (MDR)

a) This product is classified under **Class I** Medical Device per Rule 1 of Annex VIII Chapter III, meets the provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
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b) This product complies with European Standards EN 455-1:2000, EN 455-2:2015, EN 455-3:2015, and EN 455-4:2009.

2) EU Type-Examination

a) This product is classed as **Category III** of Personal Protective Equipment (PPE) according to PPE Regulation (EU) 2016/425 and has been shown to comply with this Directive through the Harmonised European Standards EN 420:2003+A1:2009, EN ISO 374-1:2016, EN ISO 374-2:2016 and EN ISO 374-5:2016.

b) Notified Body responsible for certification and Module B compliance is SATRA Technology Europe Ltd, Bracetown Business Park, Clonee, Dublin D15 YN2P, Ireland. (2777).

c) Notified Body responsible for Quality Assurance of the Production Process (Module D) is SATRA Technology Europe Ltd, Bracetown Business Park, Clonee, Dublin D15 YN2P, Ireland. (2777).

d) EU Declaration of Conformity is accessible at https://www.santex.es.

3) Marking

a) **Micro Organism Hazards Pictogram:** EN ISO 374-5:2016 Protect against Bacteria, Fungi and Virus. No penetration of bacteriophages through the specimen and the following pictogram is applied.

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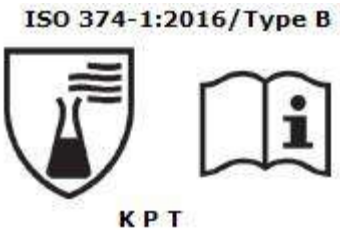
b) **Chemical Hazards Pictogram:** EN 16523-1:2015; Additional information on chemical resistance obtainable from manufacturer.

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 shall be used with reference to clause 6.3 of ISO 374-1.



4) Performance and Limitation of Use

a) This product had been tested in accordance with EN ISO 374-5:2016.
Protection against bacteria and fungi - Pass
Protection against viruses - Pass

b) Gloves had been tested in accordance with EN 16523-1:2015 resistance to permeation by chemicals and achieved the following performance levels: -

Chemicals	Performance Level
Toluene (F)	1
40% Sodium Hydroxide (K)	6
30% Hydrogen Peroxide (P)	2
37% Formaldehyde (T)	5

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 (except in cases where the glove is equal to or over 400mm – where the cuff is tested also) 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.

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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 can be the most important factor to consider in selection of chemical resistant gloves.

v) Before usage, inspect the gloves for any defect or imperfections.

c) This product provides protection against Bacteria, Fungi and Virus. The gloves had been tested in with 16604:2014 the requirements of 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.

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

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

5) 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.

6) Handling and Storage

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

7) Shelf life

The shelf life of product is 3 years from date of manufacture.