

Examination gloves, Nitrile SENSE, blue

REF: 210258 XS/S/M/L/XL

Nitrile examination glove for single use, blue. Waterproof personal protective glove against minimal chemical risks and microorganisms.

Key Features:

- Thin powder-free nitrile glove, ambidextrous and with rolled rim for extra cuff strength.
- Good viral barrier properties, protects against variety of chemicals.
- Excellent tactile sensitivity, enhanced wet and dry grip with microtextured fingertips.
- Excellent fit, easy to don and remove.
- Free of latex, powder and proteins, good alternative to those suffering from type I allergies.
- The gloves are suitable for all food contact.



Recommendations for use:



Basic

procedures

and wards



Basic

cleaning



Wash Food handling

MEDICAL	2017/745 (EU)	CLASS I	AQL 1,5
PPE	2016/425 (EU)	CATEGORY III	AQL <1,5

REF	DESCRIPTION	SIZE CODE	OVERALL LENGTH	PACK COUNT dispenser/carton
210258XS	Examination gloves, Nitrile Sense, blue, XS		240 mm	200/2000
210258S	Examination gloves, Nitrile Sense, blue, S		240 mm	200/2000
210258M	Examination gloves, Nitrile Sense, blue, M		240 mm	200/2000
210258L	Examination gloves, Nitrile Sense, blue, L		240 mm	200/2000
210258XL	Examination gloves, Nitrile Sense, blue, XL		240 mm	180/1800

Sales Unit: Transport Carton

Regulations

The product complies with legal requirements for medical devices and personal protective equipments.

EN ISO 374-5:2016 EN ISO 374-1:2016 TU VIRUS			
REACH regulation:	The products covered by this data sheet does not contain any substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), including any of the Substances of Very High Concern (SVHC) as listed in the latest available version of the Candidate List published by European Chemicals Agency (ECHA).		
Freedom of holes: EN 455-1	AQL 1.5		
Force at break (N): EN 455-2	\geq 6.0 before ageing \geq 6.0 after ageing		
Biological evaluation: EN 455-3	Total quantity of powder residues for powder-free glove < 2 mg/glove		
Compliance with legal requirements:	Medical Device Regulation (EU) 2017/745, Class I Regulation (EU) 2016/425 on Personal Protective Equipment, Category III EC Declaration of Conformity for Personal Protective Equipment: www.onemed.com/what-we-do/doc-selefa		
Compliance with product standards:	EN 455: 1 – 4		
Chemical resistance:	Tested in accordance with EN 374-3 and/or EN 16523-1		
Food safety:	Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food		
Other tests performed:	Air leak and Water leak according to EN 374-2 (Level 2) Chemicals residue Cytotoxicity according to EN ISO 10993-5 Irritation and skin sensitization according to EN ISO 10993-10 Dexterity, length and pH according to EN 420 Mechanical performance according to EN 388 Microbiological quality RoHS compliance Resistance to degradation by chemicals according to EN 374-4 Viral penetration according to EN 374-5 and ASTM F1671		
Quality standards:	EN ISO 13485		
Label information and packaging compliance:	EN ISO 15223-1, EN 1041 and EN 420		

Material

Product Part	Raw Material & Characteristic
Palm	Acrylonitrile-butadiene (Nitrile), blue, single wall thickness min. 0.05 mm
Finger	Acrylonitrile-butadiene (Nitrile), blue, single wall thickness min. 0.08 mm

Version: 20200326 rev 5

Warnings and Recommendations

Warnings:	The product is single use. If reused, the performance of product may deteriorate and cross contamination may occur. The product contains dithiocarbamates – not to be used in case of hypersensitivity to these substances.		
Storage Recommenda- tion	Recommended storage in clean, dry space in ambient temperature. Products should be protected from direct sunlight, other intensive light sources and ozone		
Disposal Recommenda- tion	Dispose in accordance with local regulations.		
Shelf Life EN 455-4	5 Years		

Packing Information

Package	Material	Size (L x W x H) mm
Single Pack	N/A	N/A
Dispenser Pack	Cellulose, TCF quality	242 x 122 x 75 mm
Transport Carton	Cellulose, TCF quality	385 x 252 x 252 mm
Packing Tape	Transparent, PVC-free	N/A

Barcodes

ONEMED

REF	Single Pack	Dispenser	Transport Carton
210258 XS	N/A	6 "438129"353617"	6 438129 553611
210258 S	N/A	6 "438129"353624"	6 438129 553628
210258 M	N/A	6 438129 353631	6 438129 553635
210258 L	N/A	6 438129 353648	6 438129 553642
210258 XL	N/A	6 438129 353655	6 438129 553659



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