



Examination Gloves, Vinyl REGULAR

REF: 210282 XS/S/M/L/XL

Powder-free vinyl examination glove for single use.

Key Features:

- ▶ Ambidextrous and with rolled rim for extra cuff strength
- ▶ Powder free and latex free
- ▶ Good alternative to those suffering from type I and accelerator related type IV allergies



Recommendations for use:



Basic procedures
and ward



Wash



Basic
cleaning

REF	DESCRIPTION	SIZE CODE	OVERALL LENGTH	PACK COUNT dispenser/carton
210282XS	Examination gloves, Vinyl REGULAR, XS		240 mm	150/1500
210282S	Examination gloves, Vinyl REGULAR, S		240 mm	150/1500
210282M	Examination gloves, Vinyl REGULAR, M		240 mm	150/1500
210282L	Examination gloves, Vinyl REGULAR, L		240 mm	150/1500
210282XL	Examination gloves, Vinyl REGULAR, XL		240 mm	150/1500

Sales Unit: Transport Carton

Technical Summary

Regulations

The product complies with legal requirements for medical devices.



single use only

EN 455

REACH regulation:	The products covered by this data sheet do not contain carcinogenic, mutagenic or toxic for reproduction substances, 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	Before ageing $\geq 3,6$ N After ageing $\geq 3,6$ N
Biological evaluation: EN 455-3	Total quantity of powder residues for powder-free glove < 2 mg/glove
Compliance with legal requirements:	Medical Devices Directive 93/42/EEC, Class I
Compliance with product standards:	EN 455: 1 – 4
Food safety:	Approved for use in food industry in accordance with EU regulations 1935/2004 and 10/2011 and its amendments. Suitable for handling dry and aqueous foods – not for handling fatty foodstuffs.
Quality standards:	The product is manufactured in compliance with EN ISO 13485
Label information and packaging compliance:	In accordance with EN ISO 15223-1 and EN 1041

Material

Product Part	Raw Material & Characteristic
Palm	Polyvinyl chloride, single wall thickness min. 0,05 mm
Finger	Polyvinyl chloride, single wall thickness min. 0,05 mm











Warnings and Recommendations

Warnings:	The product is single use. If reused, the performance of product may deteriorate and cross contamination may occur.
Storage Recommendation	Recommended storage in clean, dry space in ambient temperature. Products should be protected from direct sunlight, other intensive light sources and ozone
Disposal Recommendation	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	240 x 120 x 80 mm
Transport Carton	Cellulose, TCF quality	420 x 250 x 255 mm
Packing Tape	Transparent, PVC-free	N/A

Barcodes

REF	Single Pack	Dispenser	Transport Carton
210282XS	N/A	 6 438129 353389	 6 438129 553383
210282S	N/A	 6 438129 353334	 6 438129 553338
210282M	N/A	 6 438129 353341	 6 438129 553345
210282L	N/A	 6 438129 353358	 6 438129 553352
210282XL	N/A	 6 438129 353396	 6 438129 553390

DECLARATION OF CONFORMITY

replaces version dated: 15.05.2020

We

OneMed Group Oy, Metsäläntie 20, FI-00320 Helsinki

declare under our sole responsibility that following CE marked products, all belonging to

- **class I** according to Annex VIII of the **Regulation (EU) 2017/745 on medical devices**, and to
- **category III** according to the **Regulation (EU) 2016/425 on personal protective equipment**

Basic UDI-DI	6438129B0001GU
Intended purpose	Intended to be worn on the hands to provide a barrier against potentially infectious materials and other contaminants and protection for a variety of chemicals, and to provide barrier from cross contamination The gloves are disposable and designed for transient use.
Item number (REF)	Trade and product name
210252 sizes XS, S, M, L, XL	SELEFA® Nitrile exam gloves, SMART, white (200 pcs)
210253 sizes XS, S, M, L, XL	SELEFA® Nitrile exam gloves, SMART, blue (200 pcs)
210255 sizes XS, S, M, L, XL	SELEFA® Nitrile exam gloves, SMART, blue (100 pcs)
210256 sizes XS, S, M, L, XL	SELEFA® Nitrile exam gloves, SMART, white (150 pcs)
210258 sizes XS, S, M, L, XL	SELEFA® Nitrile exam gloves, SENSE, blue (200 pcs)
210259 sizes XS, S, M, L, XL	SELEFA® Nitrile exam gloves, SENSE, black (200 pcs)

to which this declaration relates, are in conformity with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices as well as of the Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment, and with following harmonized standards and common specifications¹:

EN ISO 13485	Medical Devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971	Medical Devices – Application of risk management to medical devices
EN 1041	Information supplied by the manufacturer with medical devices
EN ISO 15223-1	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General requirements
EN 420	Protective glove. General requirements and test method
EN 455-1	Medical gloves for single use. Part 1 – Requirements and testing for freedom from holes
EN 455-2	Medical gloves for single use. Part 2 – Requirements and testing for physical properties
EN 455-3	Medical gloves for single use. Part 3 – Requirements and testing for biological evaluation
EN 455-4	Medical gloves for single use. Part 4 – Requirements and testing for shelf life determination
EN ISO 374-1	Protective gloves against chemicals and micro-organism. Part 1 - Terminology and performance requirements for chemical risks
EN ISO 374-5	Protective gloves against dangerous chemicals and micro-organisms. Part 5 - Terminology and performance requirements for micro-organisms risks

¹Relevant harmonized standards with latest applied revisions listed in Appendix 1

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The products are subject to the conformity assessment procedure conformity to type based on Module C2 under surveillance of the notified body **2777 SATRA Technology Europe Limited, Bracetown Business Park, Clonee, D15YN2P, Republic of Ireland**, and issued the EU Type Examination certificate 2777/10892-02/E02-01. Type C glove according to EN 374-1:2016.

Place and date of issue

Göteborg 01.07.2020

Name and signature of the authorized person



Martin Hillbratt
Quality Director