

# PPE COVID-19

## PRODUCT LEAFLET

PRODUCT CODE	G301-G18-01 G301-G16-01 G301-G17-01
DESCRIPTION	Examination gloves latex powdered, small Examination gloves latex powdered, medium Examination gloves latex powdered, large
UNIT OF MEASURE	100 pieces



**PRODUCT DESIGN** Creamy white color gloves made from natural rubber latex, textured at fingertip area, ambidextrous in nature, non-toxic, non-irritant and non-sterile. For single use only.

### DIMENSIONS

#### Physical dimensions

Length	≥240mm
Thickness palm	0.08
Thickness finger	0.08
Palm width	
Small	80 ± 10 mm
Medium	95 ± 10 mm
Large	110± 10 mm

Characteristics	Inspection level	Limits	Method	AQL
Freedom from holes	G-1	Free from holes	EN 455-1	1.5
Tensile strength	N=13 (S-2)	Before ageing: NLT 18 MPa After ageing: NLT 14 MPa	ASTM D3578	4
Ultimate elongation	N=13 (S-2)	Before ageing: NLT 650 % After ageing: NLT 500 %	ASTM D3578	4
Force at break	N=13 (S-2)	Before ageing: NLT 6 N After ageing: NLT 6 N	EN 455-2	N/A
Stress at 500 % elongation	N=13 (S-2)	NMT 5.5 MPa	ASTM D412 (ASTM D3578)	4
Extractable protein content	N=3	Total protein content: NMT 200 µg / dm <sup>2</sup>	EN 455-3 (ASTM D3578)	N/A
Powder amount	N=2	Powdered content: NMT 10 mg / dm <sup>3</sup>	EN 455-3 (ASTM D3578)	N/A

**INTENDED USE** Gloves intended for use in the medical field to protect patient and user from cross-contamination during conducting medical examinations, diagnostic and therapeutic procedures, and handling contaminated medical materials.

**INSTRUCTION FOR USE** After donning, remove powder by wiping gloves thoroughly with a sterile wet sponge, sterile wet towel, or other effective method.

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DISPOSAL                      Dispose as medical waste in accordance with hospital, administrative and/or local government regulations and policies.

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REGULATORY                      EU Medical Device Directive (declaration of conformity as per MDD 93/42/EEC risk class I)  
APPROVAL                      ISO 13485:2016 & ISO 9001:2015

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APPLICABLE                      Product is complying with the following standards  
STANDARDS                      EN455 (Medical gloves for single use)  
   ASTM D3578 (Standard specification for Rubber examination gloves)  
   EN ISO 10993 (Biological evaluation of medical devices)

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STORAGE                      Keep in cool, dry place and keep away from direct sunlight. Recommended storage 0°C -30°C, however excursion allowed till 40°C.

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SHELF LIFE                      60 months

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PACK SIZE                      100 pieces per box

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PRODUCT PHOTO

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