



Surgical Polyisoprene Gloves – Victor

Art. No. 1000029140-1000029148



Description

Surgical glove
Polyisoprene
Powder-Free
Sterile
Textured surface
Low grip
With rolled cuff
Curved fingers
Hand specific
Single use

CE

Dual CE-labelled according to:
Medical Device Regulation (EU) 2017/745 Class IIa
PPE Regulation (EU) 2016/425, Type B CAT III (IKMPT)
AQL 0,65 according to the requirements in the harmonized standard EN 455-1
Produced in Malaysia under ISO 9001, ISO14001 and ISO13485. Imported by ABENA A/S
EC-REP MDSS GmbH

Standards

EN 455-1, 2, 3 & 4
EN ISO 374-1:2016
EN ISO 374-2:2019
EN16523-1:2015
EN ISO 374-4:2019
EN ISO 374-5:2016 VIRUS
EN ISO 21420:2020
ASTM D6978
EN ISO 11137 (Gamma sterilization)



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Tests performed

Sensitization
Irritation
Cytotoxicity
Protein content
Powder Residual
Chemicals Residual
Force at Break
Bacteria, Fungi test & Virus

Thickness

Palm	0.19 mm (+/- 0.04)
Fingers	0.21 mm (+/- 0.04)
Cuff	0.15 mm (+/- 0.04)

Proteins

≤ 50 µg Test method Modified Lowry – EN 455-3

Powder residual

≤ 2 mg/glove

Physical properties

Force at break (EN 455-2)	
Before challenge	9 Newton
After challenge testing at 70°C for 166 hours	9 Newton

Chemical permeation

Chemical	CAS	Breakthrough time	Level
Ethyl Acetate	142-62-7	>480 min	6
Formaldehyde 37%	50-00-0	>480 min	6
Hydrogen Peroxide 30%	7722-84-1	>480 min	6
Nitric acid 65%	7697-37-2	>240 min	5
Sodium Hydroxide 40%	1310-73-2	>480 min	6

Test method used: EN 16523-1:2015

Cytostatica	Breakthrough time	Level
Carmustine 3.300 ppm	12,3 min	1
Cisplatin 1.000 ppm	>240 min.	5
Cyclophosphamide 20.000 ppm	>240 min.	5
Dacarbazine 10.000 ppm	>240 min.	5
Doxorubicin Hydrochloride 2.000 ppm	>240 min.	5
Etoposide 20.000 ppm	>240 min.	5



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Fluorouracil 50.000 ppm	>240 min.	5
Methotrexate 25.000 ppm	>240 min.	5
Mitomycin C 500 ppm	>240 min.	5
Paclitaxel (Taxol) 6.000 ppm	>240 min.	5
ThioTepa 10.000 ppm	17,4 min.	1
Vincristine Sulfate 1.000 ppm	>240 min.	5

Test method used: ASTM D6978

Art. no. / REF:	Size	Product	Feature	Length mm (+/-10)	Quantity Dispenser/carton
1000029140	5 ½	Polyisoprene surgical gloves	Powder free	290	50/200
1000029141	6	Polyisoprene surgical gloves	Powder free	290	50/200
1000029142	6 ½	Polyisoprene surgical gloves	Powder free	290	50/200
1000029143	7	Polyisoprene surgical gloves	Powder free	290	50/200
1000029144	7 ½	Polyisoprene surgical gloves	Powder free	290	50/200
1000029145	8	Polyisoprene surgical gloves	Powder free	290	50/200
1000029146	8 ½	Polyisoprene surgical gloves	Powder free	290	50/200
1000029147	9	Polyisoprene surgical gloves	Powder free	290	50/200

Storage and handling

Handling: Avoid heat, humidity, bright light and ozone

Shelf life: 3 years from production date