# DISPOSABLE NITRILE GLOVES



# TECHNICAL DATA SHEET

## **PRODUCT INFORMATION**

Nitrile Gloves 24cm Nitrile Examination Gloves. Lightweight, non-sterile, powder-free, light blue, medical device Class I, PPE class III. For single use in the work, safety, hygienic and medical sector. Suitable for food contact.





## CHARACTERISTICS

#### Dimensions

Size	Length*	Palm width	
XS	Min. 240mm	≤80mm	
S	Min. 240mm	80±10mm	
М	Min. 240mm	95±10mm	
L	Min. 240mm	110±10mm	
XL	Min. 240mm	≥110	

\*in complience with EN455-2

#### Thickness - single wall

PALM	FINGER
Min 0,05mm (avg. 0.07mm)	Min 0,05mm (avg. 0.10mm)

#### DESIGN

Material: Nitrile Powder: Powder-free Shape: Ambidextrous Cuff: Beaded cuff Color: Light blue External surface: Finger-textured Protein content: N/D Sterilization: Non-sterile

#### LOGISTIC DATA

Gloves in dispenser: 100 gloves Dispenser dimension: 20 x 11 x 6 cm Shelf life: 5 years Gloves in carton: 10 x 100 gloves Carton dimension: 22,5 x 31 x 21 cm

**Storage:** Store in original packaging in a dry and dark place at room temperature. Protect from heat, humidity, bright light and ozone.

PHYSICAL PROPERTIES			
Parameters	Aging before	After aging	
Force at break	Minimum 6N	Minimum 6N	
Elongation	Minimum 500%	Minimum 400%	
AQL	1.5		

### QUALITY MANAGEMENT

Product related standards	EN 455-1:2020, EN 455-2:2015, EN 455-3:2023, EN 455-4:2009 EN 374-1:2016, EN 374-1:2016+A1:2018, EN 374-2:2019 EN 374-4:2019, EN 374-5 :2016, EN 21420:2020, EN 16523-1:2015+A12018, ASTM D6319:2019	
Quality certificates	ISO 9001:2015, ISO 13485:2016, ISO 14001:2015, ISO 45001:2018	
Food safety	Suitable for foodstuffs in accordance to Framework Regulation (EC) No 1935/2004 German Food and Feed Code (LFGB) Recommendation of the German Federal Institute for Risk Assessment (BfR XXI) Category 3 "For short contact with foodstuffs"	
Medical Device	Medical Device, Class 1, in accordance to MDR 2017/745	
PPE	Personal protective equipment in accordance to Regulation (EU) 2016/425 CE Category III: For irreversible or mortal risks	







# **BREAKTHROUGH TIMES**

Chemical	CAS-no:	Breakthrough times in min. (EN 374-3/EN 16523-1)	Perfomance Index
Methanol (A)	67-56-1	Not tested	N/A
Acetone (B)	67-64-1	Not tested	N/A
Acetonitrile (C)	75-05-8	Not tested	N/A
Dichloromethane (D)	75-09-6	Not tested	N/A
Carbon disulphide (E)	71-15-0	Not tested	N/A
Toluene (F)	108-88-3	Not tested	N/A
Diethylamine (G)	109-89-7	Not tested	N/A
Tetrahydrofuran (H)	109-99-9	Not tested	N/A
Ethyl Acetate (I)	141-78-6	Not tested	N/A
n-Heptane (J)	142-82-5	Not tested	N/A
Sodium Hydroxide 40% (K)	1310-73-2	>480	Level 6
Sulfuric acid 96% (L)	7664-93-9	Not tested	N/A
Nitric acid 65% (M)	7697-37-2	<6	Level 0
Acetic acid 99% (N)	64-19-7	Not tested	N/A
Ammonia 25% (O)	1336-21-6	Not tested	N/A
Hydrogen peroxide 30% (P)	7722-84-1	>480	Level 6
Hydrofluoric acid 40% (S)	7664-39-3	Not tested	N/A
Formaldehyde 37% (T)	50-00-0	>480	Level 6

Cytostatic	Concentration [mg/ml]	Breakthrough time in min. (ASTM D6978-05) Report refer latest report, more chemodrugs covered	
Bleomycin Sulfate	15,0	No breakthrough up to 240min	
Busulfan	6,0	No breakthrough up to 240min	
Carboplatin	10,0	No breakthrough up to 240min	
Carmustine	3,3	23,5 min	
Cisplatin	1,0	No breakthrough up to 240min	
Cyclophosphamide	20,0	No breakthrough up to 240min	
Cytarabine	100,0	No breakthrough up to 240min	
Dacarbazine	10,0	No breakthrough up to 240min	
Daunorubicin HCL	5,0	No breakthrough up to 240min	
Docetaxel	10,0	No breakthrough up to 240min	
Doxorubicin	2,0	No breakthrough up to 240min	
Epirubicin	2,0	No breakthrough up to 240min	
Etoposid	20,0	No breakthrough up to 240min	
Fluorouracil	50,0	No breakthrough up to 240min	
Gemcitabin	38,0	No breakthrough up to 240min	
Idarubicin	1,0	No breakthrough up to 240min	
lfosamide	50,0	No breakthrough up to 240min	
Irinotecan	20,0	No breakthrough up to 240min	
Mechlorethamine HCL	1,0	No breakthrough up to 240min	
Melphalan	5,0	No breakthrough up to 240min	
Methotrexate	25,0	No breakthrough up to 240min	
Mitomycin C	0,5	No breakthrough up to 240min	
Mitoxantrone	2,0	No breakthrough up to 240min	
Paclitaxel	6,0	No breakthrough up to 240min	
Rituximab	10,0	No breakthrough up to 240min	
Thiotepa	10,0	39.7 mins	
Trisenox	1,0	No breakthrough up to 240min	
Vincristin sulfat	1,0	No breakthrough up to 240min	

### **PLEASE NOTICE**

Glove length is appropriate to the use where the risk is minimal to the wrist area.

#### USAGE

The product needs to be checked for the correct size and suitability with regard to its intended use. Before use check for damage and do not use damaged or unsuitable gloves. The gloves are intended for single use only and shall be disposed on a regular basis.

#### CAUTION

The product may cause allergic reactions on sensitive people. Particular caution must be exercised if the user has any known or suspected hypersensitivity.

The information above are to be considered as typicial values in the standard version based on the manufacturer's information. Subject to modification. The gloves shall only be used for its intended purpose.

## PRODUCTION

Manufactured in Thailand by Sri Trang Gloves (Thailand) PCL for Prosenso ApS/Eastwest Medico ApS., Denmark.

#### **TECHNICAL DATA SHEET ISSUED BY**

Eastwest Medico Aps Gotfred Rodes Vej 2 2920 Charlottenlund Denmark

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ltem no.	Size	Number	Boxes per carton
EWBLU35MST1-XS	XS	100 pieces/box	10
EWBLU35MST1-S	S	100 pieces/box	10
EWBLU35MST1-M	М	100 pieces/box	10
EWBLU35MST1-L	L	100 pieces/box	10
EWBLU35MST1-XL	XL	100 pieces/box	10

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