

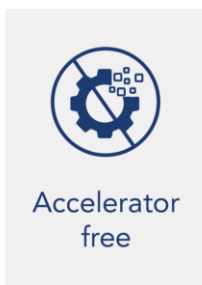
## 1140

### KOLMI COVERFEEL TOUCH - POWDER FREE NITRILE GLOVE

Class I Medical Device and Category III Personal Protective Equipment

#### FEATURES & BENEFITS



- Without accelerator to limit type IV allergies.
- Ultra comfortable glove and faster donning thanks to its internal polymer coating.
- Great elasticity and good dexterity.
- Non-slip texture for excellent grip and manipulation of objects.
- Waterproof and airtight glove.



#### INTENDED USE

- Glove intended for professional use.
- In a medical environment, this glove is used to provide a barrier against micro-organisms, between healthcare personnel, the patient, and their environment. Protection tested (permeation) against many chemotherapy agents (oncology).
- In an industrial environment, this glove is intended to protect the wearer from the tested chemicals (type B) and microorganisms (bacteria, molds and viruses).
- Powder-free, it reduces the risk of airborne contamination and limits the risk of irritation.
- Without natural latex, this glove is recommended for people allergic to it.
- This glove is suitable for food contact for any type of food.

#### TECHNICAL DESCRIPTION

Name of product:	Kolmi Coverfeel Touch
Type of product:	Single-use glove, no-sterile
Material:	Nitrile
Color:	Blue
Shape:	Ambidextrous
Edge :	Rolled
Texture :	Fingers textured
Powder :	No
Thickness of the palm:	0.07mm (±0,02mm)
Thickness of finger:	0.08mm (±0,02mm)
Length of glove:	≥ 240mm
	≥ 250 mm for XL & XXL
Unit weight (M):	3.5g
Country of manufacture:	FRANCE  
Conditioning :	Box from 100uc – Sizes XS, S, M & L
	Box from 90uc – Sizes XL & XXL

Article	Size	
1140-A	T6	XS
1140-B	T7	S
1140-C	T8	M
1140-D	T9	L
1140-E	T10	XL
1140-F	T11	XXL

## CERTIFICATIONS & STANDARDS

- Designed and distributed under an ISO 13485 & ISO 9001 certified quality system.
- Complies with the requirements of Regulation (EU) 2017/745, relating to medical devices.
- Meets EN 455-1/2/3/4 standards for non-reusable medical gloves.
- Complies with the requirements of Regulation (EU) 2016/425, relating to personal protective equipment.
- Meets EN ISO 21420, EN ISO 374-1/2/4/5, EN 16523-1, ISO 16604 standards, for protection against tested chemicals (type B), microorganisms including viruses.
- In accordance with requirements of Reg.(EC) 1935/2004 and the French decree of 5th August 2020. This glove is suitable for food contact, with all types of foodstuff.
- Tested according to ASTM D6978-05 for the evaluation of the resistance of medical gloves to permeation by tested chemotherapy drugs.
- Electrostatic properties: tested to EN 1149-1, EN 1149-2 & EN 1149-3 (results on request).

Chemical permeation data (EN 16523-1:2015+A1:2018)		
Chemicals tested	N° CAS	Performance level/ Breakthrough time
J: n-Heptane	142-82-5	Level 3, < 120 min
K: Sodium hydroxide 40%	1310-73-2	Level 6, > 480 min
T: Formaldehyde 37%	50-00-0	Level 5, > 480 min

Resistance to cytotoxic drugs (ASTM D6978-05)	
Cytotoxic molecules and concentration	Minimum hole detection time
Carmustine (BCNU) - 3.3 mg/ml	21,7 min
Doxorubicin HCl - 2.0 mg/ml	> 240 min
Cyclophosphamide - 20 mg/ml	> 240 min
Paclitaxel - 6.0 mg/ml	> 240 min
Thiotepa - 10.0 mg/ml	54,3 min
Etoposide - 20.0 mg/ml	> 240 min
Fluorouracil - 50.0 mg/ml	> 240 min
Bulsulfan - 6mg/ml	> 240 min
Irinotecan HCl - 20mg/ml	> 240 min
Vidaza (Azacytidine) - 25 mg/ml	> 240 min
Fentanyl citrate injection - 100mcg/2ml	> 240 min
Methotrexate - 25mg/ml	> 240 min
Vincristine Sulfate - 1mg/ml	> 240 min
Ifosfamide - 50mg/ml	> 240 min
Cytarabine HCl - 100mg/ml	> 240 min



## PRECAUTIONS

The device should be used on healthy skin only.

Single use, do not reuse.

After use, comply with the national regulations in force for the disposal of the device.

## COMPOSITION OF THE DEVICE

Nitrile – without sulfide or accelerator

Latex: no

BPA: no

Phthalates CMR: no

Product of animal or plant origin: no

Presence of ethylene oxide: no

## STORAGE CONDITIONS

Normal conservation and storage conditions: must not be exposed to humidity and sunlight.

Product lifespan: 3 years.

## MARKING ON THE PACKAGING



## LOGISTICS INFORMATION

CARTON SPECIFICATIONS				BOX SPECIFICATIONS			
Article	SIZE (mm)	Weight (kg)	Qty/pallet	BARCODE	SIZE (mm)	QTY / carton	BARCODE
1140-A	L340 x W250 x H260	3,2	60 boxes (6 layers of 10 boxes)	3 662 036 020 758	L250 x W121 x H64	10 dispenser boxes of 100 units	3 662 036 020 901
1140-B		3,7		3 662 036 020 765			3 662 036 020 918
1140-C		4,2		3 662 036 020 772			3 662 036 020 925
1140-D		4,7		3 662 036 020 789			3 662 036 020 932
1140-E		5		3 662 036 020 796		3 662 036 020 949	
1140-F		5,4		3 662 036 020 963		3 662 036 020 956	

