

## 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.
- Robust for greater durability.
- 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 tested chemicals (type B), radioactive particles and microorganisms (bacteria, mold 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 Care
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:	0.10mm (±0,02mm)
Thickness of finger:	0.11mm (±0,02mm)
Length of glove:	≥ 240mm ≥ 250 mm for XL & XXL
Unit weight (M):	5.2g
Country of manufacture:	FRANCE  
Conditioning :	Box from 100 uc –Sizes S, M & L Box from 90uc- Sizes XL & XXL

Article	Size	
1142-B	T7	S
1142-C	T8	M
1142-D	T9	L
1142-E	T10	XL
1142-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 chemicals tested (type B) and microorganisms including viruses. EN 421 for protection against radioactive particles.
- 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 the tested chemotherapy drugs.
- Electrostatic properties: tested to EN 1149-1, EN 1149-2 & EN 1149-3 (results on request).
- Compliant with ISO 18889:2019, relating to the protection of operators handling pesticides – Category G1. Test reports are available upon 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 5, > 480 min
K: Sodium hydroxide 40%	1310-73-2	Level 6, > 480 min
T: Formaldehyde 37%	50-00-0	Level 6, > 480 min
Sulphuric acid 50%	7664-93-9	Level 6, > 480 min
Sodium hydroxide 50%	1310-73-2	Level 6, > 480 min
Peracetic acid 5%	79-21-0	Level 6, > 480 min
Cyclohexane 99%	100-82-7	Level 4, < 240 min
Isopropyl alcohol 70%	67-63-0	Level 3, < 120 min
P: Hydrogen peroxide 30%	7722-84-1	Level 2, < 60 min
Ethanol 70%	64-17-5	Level 2, < 60 min
Hydrochloric acid 37%	7647-01-0	Level 1, < 30 min
A: Methanol	67-56-1	Level 0, < 10 min
C: Acetonitrile	75-05-8	Level 0, < 10 min
L : Sulfuric Acid	7664-93-9	Level 0, < 10 min
M : Nitric Acid	7697-37-2	Level 0, < 10 min
N : Acetic Acid	64-19-7	Level 0, < 10 min
O: Ammonium hydroxide 25%	1336-21-6	Level 0, < 10 min
S : Hydrofluoric acid 40%	7664-39-3	Level 0, < 10 min
Methyl ethyl ketone (MEK) 100%	78-93-3	Level 0, < 10 min

### Resistance to cytotoxic drugs (ASTM D6978-05)

Cytotoxic molecules and concentration	Minimum hole detection time
Carmustine (BCNU) - 3.3 mg/ml	54,7 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	65,5 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.

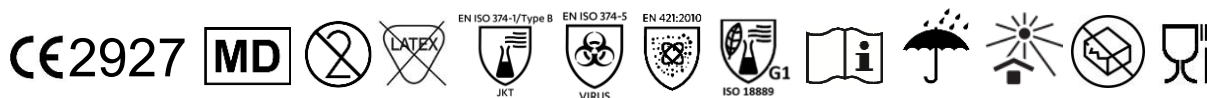
## COMPOSITION OF THE DEVICE

Nitrile – without 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 direct 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		
1142-B	L390 x l290 x H275	5,7	48 boxes	3 662 036 021 045	L255 x W135 x H73	10 dispenser boxes of 100 units	3 662 036 020 987		
1142-C		6		3 662 036 021 052			3 662 036 020 994		
1142-D		6,5		3 662 036 021 069			3 662 036 021 007		
1142-E		6,7		3 662 036 021 076		3 662 036 021 014			
1142-F		7,1				3 662 036 021 083		10 dispenser boxes of 90 units	3 662 036 021 021