Technical sheet

1142 KOLMI COVERFEEL CARE - 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.
- Robust for greater durability.
- Non-slip texture for excellent grip and manipulation of objects.
- Waterproof and airtight glove.

PureFlex® TECHNOLOGY

Accelerator free

MADE IN FRANCE

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

DOMINIQUE DUTSCHER SAS

Legal manufacturer: MEDICOM SAS | Boulevard de la Chanterie, 49124 Saint Barthélemy d'Anjou, France
Tel: 02.41.96.34.34 - Fax: 02.41.96.34.52 - sales.support.pro.eu@medicom.com - www.medicom-eu.com
Production plant and distributor: ManiKHeir - MEDICOM Group | 21 rue du 8 mai 1945, 72310 Bessé sur Braye, France
Tel: 02.59.29.09.40 - Fax: 02.59.29.09.41

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
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
O: Ammonium hydroxide 25%	1336-21-6	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

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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.

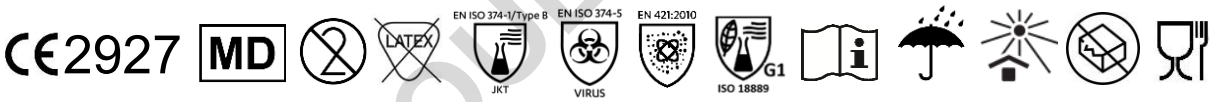
COMPOSITION OF THE DEVICE

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 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		10 dispenser boxes of 90 units	3 662 036 021 014
1142-F		7,1		3 662 036 021 083			3 662 036 021 021

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