# Medicom® Technical sheet

## 1144 COVERFEEL CARE LONG - 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.
- Robust for greater durability
- Long cuff for optimal protection.
- 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 Long 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: | ≥ 290mm<br>≥ 300 mm for XL & XXL |
| Unit weight (M): | 6g |
| Country of manufacture: | FRANCE |
| Conditioning : | Box from 100 uc - Sizes S, M & L<br>Box from 90uc- Sizes XL & XXL |

| Article | | Size |
|---|---|---|
| 1144-B | T7 | S |
| 1144-C | T8 | M |
| 1144-D | T9 | L |
| 1144-E | T10 | XL |
| 1144-F | T11 | XXL |

DOMINIQUE DUTSCHER SAS

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**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.

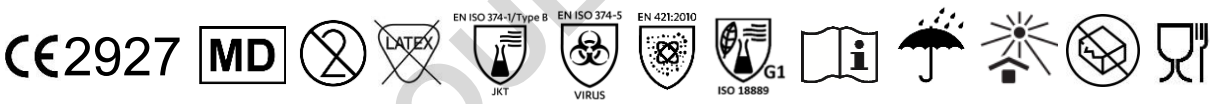
## COMPOSITION OF THE DEVICE

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** |
| 1144-B | L393 x W288x H307 | 7,9 | 40 boxes (5 layers of 8 boxes) | 3 662 036 021 779 | L290 x W135 x H73 | 10 dispenser boxes of 100 units | 3 662 036 021 717 |
| 1144-C | | 8,3 | | 3 662 036 021 786 | | | 3 662 036 021 724 |
| 1144-D | | 9 | | 3 662 036 021 793 | | | 3 662 036 021 731 |
| 1144-E | | 9,2 | | 3 662 036 021 809 | | 10 dispenser boxes of 90 units | 3 662 036 021 748 |
| 1144-F | | 9,8 | | 3 662 036 021 816 | | | 3 662 036 021 755 |

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