

DECLARATION OF CONFORMITY TO FOOD CONTACT

The holder, established in France:

Medicom SAS Boulevard de la Chanterie 49124 Saint Barthélemy d'Anjou France

declare that the product covered by this declaration, described below:

1144 - Coverfeel Care Long
Nitrile glove, powder-free, non-sterile
Sizes XS to L - 10x100 (1000 units) and XL to XXL - 10x90 (900 units)

belonging to the rubber family,

comply with the following provisions:

- Regulation (EC) 1935/2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC
- Regulation (EC) 2023/2006 on good manufacturing practice (GMP) for materials and articles intended to come into contact with food
- French decree of 5 August 2020 on rubber materials and articles intended to come into contact with food

This declaration of conformity has been drawn up on the basis of the following elements:

- Declarations of the suppliers of raw materials (composing the material subject to the declaration) and/or the manufacturer(s) carrying out one or more processing operations
- Ingredients, starting monomers and additives used in the manufacture belonging to the positive lists. Analyses of global migration below 10mg/dm² (simulants A – B – D2)
- Analyses of restricted substances (including specific migrations) below SML
- Maintaining the organoleptic properties of food in contact with the glove

This glove is suitable for contact with all types of food (2h - 40°C), without any particular restrictions.

For all intents and purposes, we declare that the product covered by this declaration does not contain bisphenol A.



This compliance is subject to compliance with the conditions of storage, handling and use recommended by Medicom SAS and taking into account the particular characteristics of the glove. In the event of a change in the physicochemical properties of the food in contact with the glove, of a modification of the said food, of a modification of the conditions of contact (temperature, duration, etc.), the user must ensure that the glove remains suitable for use.

This declaration is established in application of article 16 of regulation 1935/2004/EC, article 12 of the French decree of 5 August 2020, as well as decree n°2008/1469 of 30/12/2008 modifying decree n°2007-766 concerning the application of the code of consumption with regard to materials and objects intended to come into contact with food.

This declaration is valid for a period of 5 years. It will be renewed beforehand if compliance with the above is no longer assured.

Signed for and on behalf of: Sandrine ENGELS, President of Medicom Europe

Name: Yannick CHEVALIER Place of Issue: Saint Barthélemy d'Anjou

Function: European Quality, Regulatory and R&D Director Issue date: 2024/08/20

Signature: (1) / Expiry date: 2029/08/19