

DECLARATION OF CONFORMITY 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:

1191N - SafeTouch Vitals
Blue nitrile glove, powder-free, non-sterile - Sizes XS to XL - 10x200 (2000 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 foodstuffs
- **French decree of 5 August 2020** on rubber materials and articles intended to come into contact with foodstuffs

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 foodstuffs in contact with the glove

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

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

MEDICOM SAS

Boulevard de la Chanterie – BP 10059 – 49181 Saint Barthélemy d'Anjou Cedex
Tel : 02.41.96.34.34 Fax : 02.41.96.34.53

SAS au capital de 1 214 000 € - RCS ANGERS 523 019 354 – Siret : 52301935400035 – Code APE 1395Z - TVA intra FR42523019354

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 foodstuffs in contact with the glove, of a modification of the said foodstuffs, 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 foodstuffs.

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



Yannick Chevalier
European Quality, Regulatory and R&D Director

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