

DECLARATION OF COMPLIANCE

TO WHOM IT MAY CONCERN

PRODUCT: SANITAS BLACK NITRILE GLOVES (ALL SIZES)

We, GR SARANTIS SA, certify that the products mentioned above, comply in all respects with the requirements of the following:

- EC Regulation framework 1935/2004, on materials and articles intended to come into contact with food.
- EU Commission Regulation 10/2011, on plastic materials and articles intended to come into contact with food.
- BfR XXI (01.07.2016) Commodities based on Natural and Synthetic Rubber, Category 3
- EC Directive 1994/62 and its amendments, on packaging and packaging waste.

Raw material(s) identity:

Raw material:	NITRILE RUBBER
---------------	----------------

Information about substances, subjected to restrictions in food:

-

Specifications on the use of product:

Suitable for short-term contact only (10 minutes maximum), with all types of food, at ambient and freezing temperatures.

Non-sterile product.

Restrictions of temperature and time, in contact with food:

The overall migration has been checked on finished articles and found below the maximum limits of EU Commission Regulation 10/2011 and BfR XXI (Category 3), using the following simulants &

Food simulant	Contact time & temperature
Ethanol 10% v/v	10 minutes, at 40°C
Acetic acid 3% w/v	10 minutes, at 40°C
Vegetable oil	10 minutes, at 40°C
Distilled water	10 minutes, at 40°C

Storage conditions:

Products should be stored at room temperature, away from direct sunlight and excessive heat, above 37°C.

Products should not be used after their expiry date.

Manufacturing and packaging are carefully controlled and inspected, using procedures specified by a Formal Quality System, which conforms to the requirements of EN ISO 9001:2008.

The products are not harmful for humans if used correctly, according to their instructions for use.

The present declaration is valid, when the product is used in the above described and specified conditions, provided that its handling and storage conditions are also appropriate for the preservation of the product's specific characteristics.

The present declaration is addressed to your company and it is valid only when signed by us.

The Declaration of Compliance is valid as of the date specified below and it will be replaced only in case of any change in used substances, or when the relevant legislation is modified and updated in such a manner, so that a new evaluation of the Declaration of Compliance is required.

Date: 12.05.2020

On behalf of GR SARANTIS SA

Paschalis Grammatopoulos
TPD Specialist Household

GR. SARANTIS S.A.

26, AMAROÚSIU - HALANDRIU STR.

151 25 MAROUSSI, ATHENS, GREECE

TEL: +30 210 6173000 - FAX: +30 210 6197081

e-mail: gr-info@sarantisgroup.com

V.A.T. NUMBER: EL094011001