

Declaration of Conformity to EU Food Contact Articles Regulation

Manufacturer Blue Sail Medical Co., Ltd
Address No.21 Qingtian Road, Qilu Chemical Industrial Park,
 Zibo City, Shandong Province, China 255414
Product & Identification Disposable Nitrile Gloves

Declaration of compliance with**•Regulation (EC) No.1935/2004 -**

on materials and articles intended to come into contact with food.

•Council of Europe Resolution AP (2004) 4 -

Rubber products intended to come into contact with foodstuffs.

This Disposable Nitrile Gloves has been manufactured with Nitrile Latex, other starting substances and additives that are authorised under Council of Europe Resolution AP (2004) 4.


Information about the compliance of substance used that are subject to any restriction or specification	
Compliance with overall migration limit	Overall migration is below 10mg/dm ² under standard testing condition laid down in Council of Europe Resolution AP (2004) 4.
Compliance with specific migration limit	Specific migration of Primary aromatic amine, Nitrosamine and Nitrosatable substances is ND under the standard testing condition laid down in Council of Europe Resolution AP (2004) 4.
Individual substances	The test result of Nitrosamine and Nitrosatable substances is ND under the standard testing condition laid down in Europe Resolution AP (2004) 4.

Intended use and Limitations

- Type of foods/drinks intended to come in contact with the material are the food that have a hydrophilic character and are able to extract hydrophilic substances.
- Type of foods/drinks NOT intended to come in contact with the material are strongly acidic foods, and hot liquids.
- The glove is single-use.

Identification of the person authorized to sign on behalf of the Legal Manufacturer

Signed by:



Robin Liu

Quality Director

10/01/2020