



山东英科医疗制品有限公司
Shandong Intco Medical Products Co., Ltd.

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INTCO- NBR-FDOC

版本 Ver.

A1

Declaration of Conformity for Food Contact

Declares that the disposable Nitrile gloves, made of NBR latex as main material, that comply with the provisions of Regulation (EC) 1935/2004, (EU) 10/2011 and applicable national regulations. When used as specified, the overall migration and the specific migrations are below the legal limit according to Regulation (EU) 10/2011. Regulation (EU) No. 10/2011 does not apply to nitrile gloves with regard to the requirements for materials and raw materials, it is only applicable in relation to the migration tests.

The Nitrile gloves may be used safely for the preparation and handling of foodstuff.

Types of food with which it is intended to be put in contact have Food simulant A, B, D2.

Sinulants	Test condition	Results
Food simulant A(10% Ethanol)	40°C 2h	<10mg/dm ²
Food simulant B (3% Acetic acid)	40°C 30min	<10mg/dm ²
Food simulant D2 (Olive oil)	40°C 2h	<10mg/dm ²

Note: Restricted substances and dual-use substances are not included. For substances that are not included in the Union list (Annex I of Regulation (EU) 10/2011 in its current version), the national provisions such as the recommendation of BfR and the requirements of Section 31 (1) LFGB are still valid. The disposable nitrile examination gloves are consumer goods based on natural and synthetic rubber.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: Shandong Intco Medical Products Co., Ltd.

Address: Qiwang Road, Naoshan Industrial Park. Qingzhou, Shandong, China.

This Declaration of conformity is valid for three years: 6 / Jan / 2021 to 5 / Jan / 2024. If there is a change in the declaration information, this declaration is invalid.

Shandong 2021-06-07
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Place , date

Rick Cheng Quality Manager

Legally binding signature, Function

