

## EU & FDA REGULATORY COMPLIANCE STATEMENT

### FOR GLOVES INTENDED TO COME INTO CONTACT WITH FOOD

#### DECLARE THAT THE NEW PERSONAL PROTECTIVE EQUIPMENT DESCRIBED HEREAFTER:

SHOWA 234X



#### SIMULANTS

A, B, C, D1, D2 of Regulation No.10,2011 for Plastic Materials and Articles in contact with food.

#### FOOD TYPES

All dry, aqueous, acidic, alcoholic and fatty foods.

#### TESTING CONDITIONS

2 hours at 70°C, Repeat use (or equivalent)

We confirm that the above-mentioned product is in conformity with the applicable requirements of the following regulations and standards for the intended food contact conditions:

- Regulation (EC) no.1935/2004 on Materials and Articles intended to come into contact with food including Article 3 (General requirements) and Article 17 (Traceability).
- Regulation (EC) no. 2023/2006 on Good Manufacturing Practice for materials and articles intended to come into contact with food.
- French regulatory requirements for food contact rubber – (Order of the 5th August 2020.)
- BfR Recommendation XXI XXI/1 (1st February 2023) – Commodities based on natural and synthetic rubber.
- Italian Ministerial Decree of 21 March 1973.
- Netherlands regulatory requirements, Chapter III of the Dutch packaging and food utensils regulations (RVG) for rubber products in contact with food (Staatscourant No. 8531 of the 27/03/2014).
- Spanish Royal Decree 847/2011.
- Compositional and extraction requirements of FDA 21 CFR 177.2600 Rubber articles intended for repeated use.

This compliance statement is based on information received from material suppliers, the overall and specific migration testing undertaken, the FDA extraction testing undertaken to the requirements of 21 CFR 177.2600, specific tests to the 2020 French Order and quality control systems in place. Supporting documents are available and can be disclosed to the competent authority on request.

When used as intended, the overall migration and specific migration of substances subject to restriction do not exceed the legal limits (calculated as 6 dm<sup>2</sup> glove per 1kg of food). No migratory dual use food additives subject to a quantitative or compositional restriction in food (Directives 2008/60/EC, 95/45/EC and 2008/84/EC) are associated with these gloves.



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Signed for and on behalf of SHOWA Best Glove Inc.

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