

## EU & FDA REGULATORY COMPLIANCE STATEMENT

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

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

SHOWA 6112PF



#### SIMULANTS

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

#### FOOD TYPES

All dry, aqueous and fatty foods

#### TESTING CONDITIONS

2 hours at 70° C, repeat Use

is in conformity with the provisions of:

- 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 (April 2022) – 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.

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 1 kg of food).

This compliance statement is based on information received from material suppliers, migration testing undertaken according to Directive 82/711/EEC, 85/572/EEC and Regulation 10/2011 and quality control systems in place at SHOWA. Supporting documents are available and can be disclosed to the competent authority on request.



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**EIJI HATAOKA**  
RA/QA Technical Manager  
SUS

Signed for and on behalf of SHOWA Best Glove Inc.

12/06/2026  
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