

## EU & FDA REGULATORY COMPLIANCE STATEMENT

FOR GLOVES INTENDED TO COME INTO CONTACT WITH FOOD

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

**SHOWA 8005PF EBT**



### **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

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

- 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.
- Council of Europe Resolution AP (2004)4 on Rubber Products intended to come into contact with foodstuffs.
- BfR Recommendation XXI - Commodities based on natural and synthetic rubber.
- French regulatory requirements for food contact rubber - (Arrêté du 5 août 2020 relatif aux matériaux et objets en caoutchouc destinés à entrer en contact avec des denrées alimentaires)
- Italian Ministerial Decree of 21 March 1973, (Disciplina igienica degli imballaggi, recipienti, utensili, destinati a venire in contatto con le sostanze alimentari o con sostanze d'uso personale. G.U. n. 104 del 20 aprile 1973 as amended.)
- 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, EU migration testing undertaken according to EU Regulation 10/2011, FDA extraction testing to the requirements of 21 CFR 177.2600 and quality control systems in place at Showa Glove. 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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**EIJI HATAOKA**  
RA/QA Technical Manager  
SUS

Signed for and on behalf of SHOWA Best Glove Inc.

20/05/2026  
579Edison  
Street  
Menlo,GA  
30731USA

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**DATEISSUED**