

## EU & FDA REGULATORY COMPLIANCE STATEMENT

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

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

#### SHOWA 7502PF



#### SIMULANTS

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

#### FOOD TYPES

All types of foods

#### TESTING CONDITIONS

2 hours at 70° C, repeated 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.
- Council of Europe Resolution AP (2004)4) on rubber products intended to come into contact with foodstuffs.
- Compositional and extraction requirements (distilled water and n-hexane) of FDA 21 CFR 177.2600 Rubber articles intended for repeated use
- French regulatory requirements for food contact rubber – (Order of the 5th August 2020).
- BfR Recommendation XXI -Commodities based on Natural and Synthetic Rubber.
- 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

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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**BRIAN MOSELEY**

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SAO

Signed for and on behalf of SHOWA Best Glove Inc.

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