

## 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 – 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: Materials and articles intended to come into contact with food.

Regulation (EC) No 2023/2006: Good Manufacturing Practice for Materials and Articles intended to come into contact with food.

Commission Regulation (EU) No.10/2011 on Plastic materials intended to come into contact with food including its amendments 1282/2011 and 1183/2012

French regulatory requirements for food contact rubber – (Arrêté du 9 November 1994 relatif aux matériaux et objets en caoutchouc au contact des denrées, produits et boissons alimentaires).

Germany – BfR Recommendation XXI – Commodities based on natural and synthetic rubber

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).

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).

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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