

Declaration of Compliance for Food Contact Materials

1. Product Identification: Nitrile cut level A4 chemical gauntlet with microfoam palm coating

- Product Code: **55-4173**
- Material: Nitrile Butadiene Rubber (synthetic elastomer)
- Glove Style: Gauntlet cuff with microfoam palm coating
- Intended Use: Repeated direct contact with aqueous food types

We confirm that this product listed above is in conformity with the applicable requirements of the following regulation: Regulation (EC) no.1935/2004 on Materials and Articles intended to come into contact with food. The product has been manufactured with GMP, so that under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could endanger human health, bring about an unacceptable change in the composition of the food or bring about a deterioration in organoleptic characteristics.

The glove is made from materials that meet the specifications outlined in Title 21 of the Code of Federal Regulations [21 CFR], Part 177 – Indirect Food Additives: Polymers and may be safely used in handling food as intended.

2. Applicable Regulations: This document confirms that the above product is manufactured using materials that are compliant with the applicable requirements of:

- **European Regulations:**
 - Regulation (EC) No 1935/2004 (framework for food contact materials)
 - Regulation (EU) No 10/2011 (plastics in contact with food – partially applicable)
- **US Regulations:**
 - US Food and Drug Administration (FDA) for food contact applications Title 21 CFR Part 177

3. Manufacturer: Tilsatec Limited

All sectors of the premises adhere to the company's ISO9001 system. Gloves are produced under a strict quality system where products consistently undergo a quality control procedure to ensure conformity to specified standards appropriate to their intended use. This quality system ensures the required compliance of starting materials, intermediate and finished materials

All personnel are qualified within their roles; the company considers the adequacy, knowledge and skills of its personnel to ensure highest quality standards are implemented during the manufacture of products. All qualifications and training plans are documented within the quality system. The premises and equipment used for manufacturing products are maintained to ensure compliance with the rules applicable to them. The quality control system includes regular monitoring of the systems in place. If any failure to achieve GMP is identified, corrective actions are implemented without delay and recorded for inspection by authorities where required. Documentation is held within the company with respect to specifications, manufacturing routes and processes relevant to the compliance and safety of the finished product. Gloves are labelled with a unique batch number on the inside of the material where no direct contact is made with food products. A record of the batch number is held by the company.

4. Migration Testing and Results - Testing was performed by ISO17025 accredited laboratories

European Regulation

Food Simulant	Test Conditions	Result	Report No.
Simulant A (aqueous)	10 minutes at 40 °C	Compliant	CHM2011977 2437 44652/1

US Regulations

Food Simulant	Test Conditions	Result	Report No.
Distilled Water Extraction	7 hours	Compliant	EFHZ25083410-CG-01
Distilled Water Succeeding Extraction	2 hours	Compliant	EFHZ25083410-CG-01
n-Hexane Extraction	7 hours	Compliant	EFHZ25083410-CG-01
n-Hexane Succeeding Extraction	2 hours	Compliant	EFHZ25083410-CG-01

5. Declaration

We hereby declare that the product described above complies with all relevant European food contact materials regulations, and FDA (21 CFR 177) requirements. The tests confirm that under the stated intended use conditions, the product does not release substances in quantities harmful to human health or that could change food composition or organoleptic properties.

Limitations of Use:

This declaration applies only to the product as manufactured and does not cover modifications, contamination, or misuse of the product.

It remains the responsibility of the user to ensure the glove is suitable for the specific application

Signed on behalf of (Tilsatec)



Maria Kramer, Technical Manager

Date: August 29th, 2025