

## **Declaration of Good Manufacturing Practices (GMP) for Tilsatec gloves intended to come into contact with food**

**The manufacturer:**

**Tilsatec Limited  
Flanshaw Lane, Wakefield,  
West Yorkshire, WF2 9ND, England**

Declares that the following gloves that are intended for contact with food products have been manufactured in compliance with general and detailed rules on good manufacturing practice (GMP) according to regulation 2023/2006:

### **55-5120 - Lightweight Cut Level E Foam Nitrile Palm Coated Glove**

All sectors of the premises adhere to the company's ISO9001 system. The 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.

#### **Regulation 1935/2004**

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 overall and specific migration of substances subject to restriction has been tested according to Commission Regulation (EU) No.10/2011 Annex II, and does not exceed any legal migration levels. Supporting documents are available upon request. The product has been tested against simulat food types A, B and D2 in Commission Regulation (EU) No.10/2011 for Plastic Materials and Articles in contact with all food types, aqueous and fatty foods 2 hours at 40oC for repeat use.



Maria Kramer  
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