

Declaration of Compliance for Food Contact  
Regulation (EC) No. 1935/2004 materials and articles intended to come into contact with food

We

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authorized EC representative of the manufacturer

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declare the product identified hereafter as:

**sempermed latex comfort**  
(a single-use glove made from natural rubber latex)

is compliant to the following regulations and national laws:

- **REGULATION (EC) No 1935/2004** OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC
- **German Recommendation XXI and XXI/1** for Consumer goods made of natural and synthetic rubber in contact with foodstuffs, of 01 February 2023, limiting 4.1 to 10 mg/dm<sup>2</sup> of the organic portion per requirements of BfR Recommendation XXI of 01 July 2016
- **COMMISSION REGULATION (EC) No 2023/2006** of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food

*This declaration has a validity of 2 years, subject to unexpected legal modifications.*

## INFORMATION OF DUAL-USE ADDITIVES

| E-Number | Substance                                          | Specific Maximum Level* | Specific Migration Level** |
|----------|----------------------------------------------------|-------------------------|----------------------------|
| E 171    | Titanium dioxide                                   | quantum satis           | no limit                   |
| E 470a   | Sodium, potassium and calcium salts of fatty acids | quantum satis           | no limit                   |
| E 471b   | Magnesium salts of fatty acids                     | quantum satis           | no limit                   |

\* in mg/kg food according to (EU) 1129/2011

\*\* in mg/kg food according to (EU) 10/2011

## SPECIFICATIONS ON THE USE OF THE ARTICLE

- Type(s) of food intended to be used with the product:  
All types of food.
- Time and temperature for contact with the food:  
Duration: 10min  
Temperature: 40°C
- Ration of food contact surface area to volume used to establish the compliance of the material or article:  
 $1.6 \text{ dm}^2 \cdot \text{kg}^{-1}$

## INFORMATION ON THE USE OF A FUNCTIONAL BARRIER

No functional barrier is used in this article.

Thus, the mentioned products may be used safely for the preparation and handling of foodstuffs and may stand in direct contact with all types of food for a short period of time up to 10 minutes at 40°C.

Issued: 26 August 2024



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