

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

We

HARPS Europe GmbH  
Wiedner Guertel 9-13  
1100 Vienna  
Austria

authorized EC representative of the manufacturer

HARPS Investment Asia Pte. Ltd.,  
9 Straits View  
#08-10A Marina One West Tower  
Singapore 018937

declare the product identified hereafter as:

**semperguard vinyl comfort**  
(a single-use glove made from polyvinyl chloride plastic)

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
- **COMMISSION REGULATION (EU) No 10/2011** of 14 January 2011 on plastic materials and articles intended to come into contact with food
- **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 526	Calcium hydroxide	quantum satis	no limit
E 551	Silicon dioxide	10.000	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 excluding fatty foods for which food simulants D1 (50% ethanol) and D2 (Olive oil) acc. to EU Reg. 10/2011 apply.
- Time and temperature for contact with the food:  
Duration: 2 hours  
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 dry, moist and non-fatty foodstuffs for a short period of time up to 2 hours at 40°C. Do not use the product in contact with fatty food-stuff of which food simulants D1 (50% ethanol) and D2 (Olive oil) acc. to EU Reg. 10/2011 apply.

Issued: 26 August 2024

  
Larissa Rieger  
Head of Product Management

  
Margit Wallisch  
Technical Product Management

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