

Declaration of Conformity

For plastic materials coming into contact with food

The manufacturer:

Franz Mensch GmbH
Werner-von-Siemens-Str. 2
D - 86807 Buchloe

herewith declares that the following delivered item

| | |
|--------------------|---------------------------------------|
| Item REF | 2740 |
| Description | Visitor gowns with velcro PP |
| Brand | Hygostar |
| Material | PP |
| Version | Colour: white |
| | Size: XL |
| | Length: 110cm |
| | Circumference: 130cm |

complies with the legal requirements of the current valid version of the Regulation (EU) No. 10/2011, as well as of the Regulation (EU) No. 2023/2006 and of the Regulation (EC) No. 1935/2004. If used according to specifications, both the overall migration and the specific migration levels remain below the legal limit according to Regulation (EU) No. 10/2011. The substances and raw materials used are in compliance with Regulation (EU) No. 10/2011.

Proved that the products contain substances with limitations (SML/QM) as well as Dual-Use-Substances, the limits provided in Regulation (EU) No. 10/2011 are complied. For substances that are not mentioned in the union list (Annex I of Regulation (EU) No. 10/2011 including all amendments of the Regulation (EU) NO. 2019/37), national instructions shall apply, as e.g. the German BfR Recommendations on Food Contact Materials.

Overall Migration

| Food simulant | Overall Migration | Migration Limit | Ratio |
|----------------------------|-------------------|-----------------|--------------------|
| acetic acid 3% | <3,0 | 10 | mg/dm ² |
| ethanol 10% | <3,0 | 10 | mg/dm ² |
| ethanol 95% | <3,0 | 10 | mg/dm ² |
| isooctane (oil substitute) | 4,1 | 10 | mg/dm ² |

Specification for intended use or restrictions:

Ratio of the surfaces coming into contact with the food to the volume, on the basis of which the conformity of the material has been determined: **6dm²/kg**

Type/types of food that shall come into contact with the material: **greasy, acidic, watery, alcoholic**

Type/types of food that shall NOT come into contact with the material: **none**

Duration and temperature of handling and storage when in contact with the food:

| Simulanz | Duration | Temperature |
|----------|----------|-------------|
|----------|----------|-------------|

| | | |
|----------------------------|-----------|-------|
| acetic acid 3% | 10 day(s) | 40° C |
| ethanol 10% | 10 day(s) | 40° C |
| ethanol 95% | 10 day(s) | 40° C |
| isooctane (oil substitute) | 2 day(s) | 20° C |

The traceability of the product is ensured according to Regulation (EC) No. 1935/2004, article 17, by the information of date of production and LOT-number on the marking of the product.

Signed for and on behalf of Franz Mensch GmbH,

Buchloe, 09.04.2024



Achim Theiler
Management