

## 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

<b>Item REF</b>	<b>27780</b>
<b>Description</b>	<b>Examination gowns with thumbhole   CPE</b>
<b>Brand</b>	<b>Hygostar</b>
<b>Material</b>	<b>CPE</b>
<b>Version</b>	<b>Colour: white</b>
	<b>Size: XL</b>
	<b>Length: 115cm</b>
	<b>Width: 100cm</b>
	<b>Material thickness: ~50my</b>

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
ethanol 10%	<3	10	mg/dm <sup>2</sup>
acetic acid 3%	<3	10	mg/dm <sup>2</sup>
ethanol 95%	<3	10	mg/dm <sup>2</sup>
isooctane (oil substitute)	<3	10	mg/dm <sup>2</sup>

#### 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: **10 dm<sup>2</sup>/kg**

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

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
----------	----------	-------------

Updated 05.06.2023

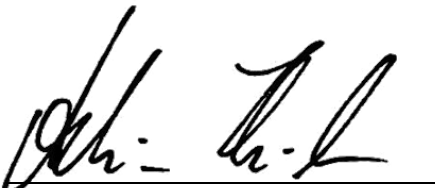
Page 1/2

ethanol 10%	10 day(s)	40° C
acetic acid 3%	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, 05.06.2023



Achim Theiler  
Management