

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	27796P
Description	Examination gowns with thumbhole Light CPE
Brand	Hygonorm
Material	CPE
Version	Colour: blue Size: XXL Length: 140cm Width: 100cm

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 ²
acetic acid 3%	<3	10	mg/dm ²
ethanol 95%	<3	10	mg/dm ²
isooctane (oil substitute)	<3	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: **10 dm²/kg**

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