

Declaration

For plastic materials that come into contact with food

The manufacturer:

Name: Unimax Medical Products Co., Ltd.

Adress: Special No.1 Liansai Road, Changshangkou Town, Xiantao City, Hubei Province, P. R. China 433024

declares that the materials and raw materials used in the products supplied supplied by us:

Art. Nr. Producer	Name	Art.-Nr. Customer	Name
UM-IG-002	Isolation gown	421-M-B	ARNOMED PP-Schutzkittel 24g
UM-IG-002	Isolation gown	421-XL-G	ARNOMED PP-Schutzkittel 24g
UM-IG-002	Isolation gown	422-M-G	ARNOMED PROTECT PP-Schutzkittel, 115x137cm, grün, 23g
UM-IG-002	Isolation gown	422-XL-B	ARNOMED PROTECT PP-Schutzkittel, 130x140cm, blau, 23g
UM-IG-PP/PE001	PP/PE lamination gown	425-Y	ARNOMED PROTECT PLUS PP/PE-Schutzkittel, 130x140cm, gelb, 30g
UM-IG-002	Isolation gown	423-XL-B	ARNOMED PROTECT PP-GOWN, BLUE, WITH KNITTED SLEEVES, 23gsm

complies with the statutory provisions of Regulation (EU) 10/2011 and all additions and amendments currently valid for this Regulation, Regulation (EU) 2023/2006 and Regulation (EC) No. 1935/2004 in its current version. The total migration as well as the specific migrations are below the legal limit according to Regulation (EU) 10/2011 when applied in accordance with the specifications. The materials and raw materials used comply with Regulation (EU) 10/2011.

Substances with restrictions (SML/QM) as well as dual-use substances are not included. For substances that are not included in the Union list (Annex I of Regulation (EU) 10/2011 and the amendment pursuant to Regulation (EU) 2019/37), the national provisions such as the recommendation of the BfR and requirements of Section 31 (1) LFGB continue to apply.

Total migration

Simulant	Total migration	Migration limit	Unit
10% Ethanol	<3	10	mg/dm ²
3% Acetic acid	<3	10	mg/dm ²
20% Ethanol	<3	10	mg/dm ²
50% Ethanol	<3	10	mg/dm ²

Rectified olive oil	<3	10	mg/dm ²
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Specification of intended use or restrictions

Ratio of the area in contact with the foodstuff to the volume on the basis of which the conformity of the material or article was established: 6 dm²/kg Type(s) of foodstuffs intended to come into contact with the material: fatty, acidic, aqueous, alcoholic

Food Type(s) of foodstuffs that should NOT come into contact with the material: none

Duration and temperature of treatment and storage in case of contact with the food:

Simulant	Duration	Temperature
10% Ethanol	2 hours	70 degree °C
3% Acetic acid	2 hours	70 degree °C
20% Ethanol	2 hours	70 degree °C
50% Ethanol	2 hours	70 degree °C
Rectified olive oil	2 hours	70 degree °C

The traceability of the product according to Regulation (EC) No. 1935/2004 Art. 17 is guaranteed by the indication of the batch number or the production data stamp on the marking.

Signed for and behalf of

Company Name: Unimax Medical Products Co., Ltd.

Date: 2024-04-07

Signature: Forest Ning

For and on behalf of
 UNIMAX MEDICAL PRODUCTS CO., LTD.
 聯賽醫用產品(湖北)有限公司

 Authorized Signature(s)