

# Declaration of Conformity in accordance with Regulation (EC) 1935/2004

the manufacturer: Ampri Handelsgesellschaft mbH Benzstr. 16 21423 Winsen (Luhe) Germany

confirms the conformity of article

### 01034 MED-COMFORT Polymer Plus

white				
disposable latex gloves powderfree				

disposable latex gloves, powderfree

with the rules of the

Regulation (EC) 1935/2004 - article 3, 5, 11, 15 and 17-, german feed and food code – LFGB, Regulation (EC) 10/2011, with regard to the migration behaviour, and the german recommendation XXI of the Federal Institute for Risk Assessment (BfR).

#### Specification of the intended use or limitations

The above-mentioned article can be used safely in the preparation and treatment of food. In this process, they may be in direct contact with the following types of food for a short time:

	acid	aqueous	alcoholic	dry	
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Restriction

	The article is not s	uitable for the follow	ving types of food:	
fatty				

The valuation basis for the glove-application is a surface-to-volume ratio of 8,4 dm<sup>2</sup> per 5kg food in accordance with the German BfR.

### sensory evaluation

simulant solution	conditioning	testing	result
coconut oil	10 minutes 40°C	odour change	no changes
coconut oil	10 minutes 40°C	flavour change	no changes
water	10 minutes 40°C	odour change	no changes
water	10 minutes 40°C	flavour change	no changes



## results of the overall migration

simulant solution	conditioning	overall migration mg/dm <sup>2</sup>	limit mg/dm <sup>2</sup>
acetic acid 3%	10 minutes 40°C	8,97 mg/dm <sup>2</sup>	10 mg/dm <sup>2</sup>
ethanol 95%	10 minutes 40°C	< 2,5 mg/dm <sup>2</sup>	10 mg/dm <sup>2</sup>
ethanol 10%	10 minutes 40°C	2,8 mg/dm <sup>2</sup>	10 mg/dm <sup>2</sup>
ethanol 10%**			

# results of the specific migration

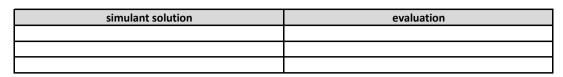
compound	simulant solution	Conditioning or other analytical methods	result	limit
Phthalates	ethanol 95%	10 minutes 40°C	not detected	
Formaldehyde	acetic acid 3%	10 minutes 40°C	< 0,02 mg/kg	≤ 3 mg/kg
Polycyclic aromatic hydrocarbons (PAH)	ethanol 95%	10 minutes 40°C	not detected	9 mg/kg
Acrylonitrile*				
Acrylonitrile*				
Butadiene*				
Butadiene*				

## Result total content

compound	simulant solution	Conditioning or other analytical methods	result	limit
Polycyclic aromatic hydrocarbons (PAH)		Ultrasonic extraction	not detected	≤ 0,2 mg/kg
Phthalates		GC-MS and/or LC-MS	not detected	
Lead		microwave digestion and analysis by ICP/MS	< 1 mg/kg	≤ 100 mg/kg
Cadmium		microwave digestion and analysis by ICP/MS	< 1 mg/kg	≤ 100 mg/kg
Primary aromatic amines (PAA)		photometric analysis	passed	
Nitrosamines	acetic acid 3%	10 minutes 40°C	0,31 μg/dm2	1 μg/dm2



### Examination of pigments ((for coloured items)



## regulation (EU) 2020/1245 heavy metals

simulant solution:	acetic acid 3%
conditioning:	1 hour 40°C

evidence	concentration in mg/kg	limit in mg/kg food or food simulant
Aluminium	< 0,1	≤ 1
Antimony	< 0,01	≤ 0,04
Arsenic	< 0,01	≤ 0,01
Barium	< 0,1	≤1
Cadmium	< 0,001	≤ 0,002
Chromium	< 0,01	≤ 0,01
Cobalt	< 0,005	≤ 0,05
Copper	< 0,5	≤ 5
Europium	< 0,01	≤ 0,05
Gadolinium	< 0,01	≤ 0,05
Iron	< 5	≤ 48
Lanthanum	< 0,01	≤ 0,05
Lead	< 0,01	≤ 0,01
Lithium	< 0,1	≤ 0,6
Manganese	< 0,1	≤ 0,6
Mercury	< 0,01	≤ 0,01
Nickel	< 0,002	≤ 0,02
Terbium	< 0,01	≤ 0,05
Zinc	0,569	≤ 5



Testreport-no. and institute:

(25421)190-490760, Bureau Veritas \*(25419)199-436777, Bureau Veritas \*\*FUFDCP2017-00420, Intertek

When used as specified, the overall migration as well as the specific migration do not exceed the legal limits. The examination was conducted in accordance with Regulation (EC) No. 10/2011 (Annex V), including all current amendments and corrections.

The requirements for materials and raw materials of the Plastic Regulation (EC) No. 10/2011 is not applicable for elastomer-protective gloves.



#### regulation (EC) 2023/2006

The above article is manufactured in accordance with Good Manufacturing Practices (GMP), i.e. they are produced and controlled with the assurance of compliance with applicable regulations and quality standards.

Ingredients with limited use in food

"dual use substances"

not applicable

Name of the substance	RefNo. (CAS- EINECS-PM and/or E-No)	Limit value [mg/kg]

The traceability according to the regulation (EC) No. 1935/2004 is ensured by the batch number.

Winsen, 11.03.2023

This declaration of conformity has a validity until

11.03.2026