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

01113 Med-Comfort Blue

blue				

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:

all types				

Restriction

The article is not suitable for the following types of food:

not applicable				

The valuation basis for the glove-application is a surface-to-volume ratio of 8,4 dm² 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/dm²	limit mg/dm²
acetic acid 3%	10 minutes 40°C	< 2,5 mg/dm²	10 mg/dm²
ethanol 95%	10 minutes 40°C	9,7 mg/dm²	10 mg/dm²
Isooctane	5 minutes 20°C	4,39 mg/dm²	10 mg/dm²
ethanol 10%*	10 minutes 40°C	2,5 mg/dm²	10 mg/dm²

results of the specific migration

compound	simulant solution	Conditioning or other analytical methods	result	limit
Primary aromatic amines	acetic acid 3%	10 minutes 40°C	< 0,02 mg/l	≤ 0,02 mg/l
Phthalates	ethanol 95%	10 minutes 40°C	not detected	
Formaldehyde	acetic acid 3%	10 minutes 40°C	< 0,02 mg/kg	≤ 3 mg/l

Result total content

compound	simulant solution	Conditioning or other analytical methods	result	limit
Polycyclic aromatic hydrocarbons (PAH)	extraction with toluene	Ultrasonic extraction	not detected	≤ 0,02 mg/kg
Bisphenol A		LC-QQQ-Analysis	< 0,1 mg/kg	≤ 0,1 mg/kg
peroxides value		titration with sodiumthiosulphate	not detected	not detected
Volatile organic matters		4 hours 105°C	< 0,1% w/w	≤ 0,5% w/w
Cadmium		microwave digestion with sulphuric	< 1 mg/kg	≤ 100 mg/kg
Zinc		Acid digestion with ICP detection	0,737%	≤ 3%
Lead		Acid digestion with ICP detection	< 0,0001%	≤ 0,003%

Examination of pigments ((for coloured items)

simulant solution	evaluation
acetic acid 3%	passed, no colour transition

regulation (EU) 2020/1245
heavy metals

simulant solution:	acetic acid 3%
conditioning:	10 minutes 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	0,1
Cobalt	< 0,005	0,05
Copper	< 0,5	5
Europium	< 0,1	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	< 3	5

Testreport-no & institute: **(25420)314-471098, Bureau Veritas**
***(25422)223-52007, Bureau Veritas**

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	Ref.-No. (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, 10.02.2023

This declaration of conformity has a validity until 10.02.2026

Rev. 00