

**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

**04020-R-M MED-COMFORT**

|     |  |  |  |  |
|-----|--|--|--|--|
| red |  |  |  |  |
|-----|--|--|--|--|

PP clip caps

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 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 | flavour change | no changes |
| water             | 10 minutes 40°C | flavour change | no changes |
|                   |                 |                |            |
|                   |                 |                |            |

**results of the overall migration**

| simulant solution | conditioning    | overall migration<br>mg/dm <sup>2</sup> | limit<br>mg/dm <sup>2</sup> |
|-------------------|-----------------|---|-----------------------------|
| acetic acid 3%    | 30 minutes 40°C | 9,2 mg/dm <sup>2</sup>                  | 10 mg/dm <sup>2</sup>       |
| ethanol 10%       | 30 minutes 40°C | <2,5 mg/dm <sup>2</sup>                 | 10 mg/dm <sup>2</sup>       |
| Isooctane         | 15 minutes 20°C | < 2,5 mg/dm <sup>2</sup>                | 10 mg/dm <sup>2</sup>       |
|                   |                 |   |                             |
|                   |                 |   |                             |
|                   |                 |   |                             |

**results of the specific migration**

| compound                | simulant solution | Conditioning or other<br>analytical methods | result              | limit      |
|-------------------------|-------------------|---|---------------------|------------|
| Phthalates              | ethanol 95%       | 30 minutes 40°C                             | not<br>determinable |            |
| Caprolactam             |                   | LC-MS analysis                              | < 1 mg/kg           | ≤ 15 mg/kg |
| Primary aromatic amines | acetic acid 3%    | 30 minutes 40°C                             | bestanden           |            |
|                         |                   |   |                     |            |

**Result total content**

| compound                                  | simulant solution          | Conditioning or other<br>analytical methods | result              | limit       |
|---|----------------------------|---|---------------------|-------------|
| Polycyclic aromatic<br>hydrocarbons (PAH) | extraction with<br>toluene | Ultrasonic extraction                       | not<br>determinable | ≤ 0,2 mg/kg |
| Phthalates                                | -                          | GC-Analysis                                 | not<br>determinable |             |
| Cadmium                                   |                            | microwave digestion                         | < 1 mg/kg           | ≤ 100 mg/kg |

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

| simulant solution | evaluation |
|-------------------|------------|
|                   |            |
|                   |            |

**regulation (EU) 2020/1245**

**heavy metals**

|                    |                 |
|--------------------|-----------------|
| simulant solution: | acetic acid 3%  |
| conditioning:      | 30 minutes 40°C |

| evidence   | concentration<br>in mg/kg | limit in mg/kg<br>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                    | ND                                      |
| 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       | < 0,5                     | 5                                       |



**Testreport-no:** (25422)220-520222

(25423)011-536560

**issued by:** 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, 12.12.2022

This declaration of conformity has a validity until 12.12.2025

Rev. 00