Declaration of Conformity
in accordance with Regulation (EC) 1935/2004 and (EU) 10/2011
for materials and plastics that come into contact with food

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

confirms the conformity of article

01194 MED-COMFORT BLUE ULTRA 300
blue
disposable nitrile 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 and the german recommendation XXI and XXI/1. of the Federal Institute for Risk Assessment (BfR) in the current version.

If the products contain restricted substances (SML/QM), the limits specified in Regulation (EU) 10/2011 are complied with. For substances not listed in the Union list (Annex I of Regulation (EU) 10/2011), national provisions continue to apply, such as the recommendations of the BfR and the requirements of Section 31 (1) LFGB.

NIAS (non-intentionally added substances) relevant to conformity were assessed in accordance with Article 19 of Regulation 10/2011 and classified as harmless.

Note on dual-use substances: Substances that are also permitted as food additives do not migrate or are present in such small quantities that they have no technological effect in the event of migration.

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	5,2 mg/dm²	10 mg/dm²
Isooctane	5 minutes 20°C	< 2,5 mg/dm²	10 mg/dm²

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:

all types				

Restriction

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

The conformity of the material or article was determined at a ratio of 6 dm^2/L type of foodstuffs that may come into contact with the material.

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.

No functional plastic barrier is used.

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.

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

Winsen, 28.05.2026

This declaration of conformity has a validity until 28.05.2029 Rev. 2026-01