

# Declaration of Compliance

## For plastic materials coming into contact with food

We herewith declare that the following products:

Article number: **DK03B50, DK03V50**

Description: **DK03B50: Face Mask 3-ply Type IIR (99%), blue, one size**  
**DK03V50: Face Mask 3-ply Type IIR (98%), green, one size**

Material: **PP nonwoven**

comply with the legal requirements of the current valid version of the Regulation (EU) No. 10/2011, as well as of the Regulation (EU) No. 2023/2006 and of the Regulation (EC) No. 1935/2004. If used according to specifications, both the overall migration and the specific migration levels remain below the legal limit according to Regulation (EU) No. 10/2011. The substances and raw materials used are in compliance with Regulation (EU) No. 10/2011.

Proved that the products contain substances with limitations (SML/QM) as well as Dual-Use-Substances, the limits provided in Regulation (EU) No. 10/2011 are complied. For substances that are not mentioned in the union list (Annex I of Regulation (EU) No. 10/2011 including all amendments of the Regulation (EU) NO. 2019/37), national instructions shall apply, as e.g. the German BfR Recommendations on Food Contact Materials.

### Overall Migration:

Simulant used	Overall Migration	Maximum Permissible Limit	unit
Distilled Water	<0.1	10	mg/kg
3 % Acetic Acid (W/V) Aqueous Solution	0.4	10	mg/kg
10% Ethanol (V/V) Aqueous Solution	<0.1	10	mg/kg
Fatty Food Simulant	<0.9	10	mg/kg

### Specification for intended use or restrictions:

- Type/types of food that shall come into contact with the material: aqueous, alcoholic, fatty and acidic foodstuff
- Type/types of food that shall NOT come into contact with the material: none
- Duration and temperature of handling and storage when in contact with the food:

Distilled Water	2 hours at 40°C
3 % Acetic Acid (W/V) Aqueous Solution	2 hours at 40°C
10% Ethanol (V/V) Aqueous Solution	2 hours at 40°C
Fatty Food Simulant	2 hours at 40°C

- Ratio of the surfaces coming into contact with the food to the volume, on the basis of which the conformity of the material has been determined: no information

Traceability of the product is ensured according to Regulation (EC) No. 1935/2004 via the number of the roll in conjunction with the date of production.

Originator:

  
Amanda Kreuzmann  
Quality Management

Buchloe, October 31, 2019

EU Declaration of Conformity for a class I medical device  
according to Annex VIII of Regulation (EU) 2017/745

The manufacturer, established in the European Community:

**TRANSPORTS KLECK SARL**  
SITE DE LA PAIX - 57440 ALGRANGE  
Tél. 03 82 85 75 75 - Fax 03 82 86 68 98  
RCS THIONVILLE B 441 421 526

declares under their sole responsibility, that the medical device(s) mentioned below

*PP- Face Mask, 3-ply, blue, green, one size*  
**Face Mask 3-ply Type IIR (99%)**  
DK03B50 DK03V50

in accordance with confirmed records, test results or certificates, complies/comply with the requirements of the Regulation (EU) 2017/745 on medical devices and with the relevant Union harmonization legislation:

EN 14683

The achieved performance levels of this surgical mask correspond to TYPE IIR.

Buchloe, May 7, 2020

  
Amanda Kreuzmann  
Quality Management