

FOOD CONTACT CONFORMITY DECLARATION
according to ISO/IEC 17050-1



Conformity assessment – Supplier's declaration of conformity General requirement
Rev. 7 of year 2025

Name, registered trade name or registered trade mark and, if already issued



NAME: PPS Manufacturing JSC
ADDRESS LEGAL SITE: Sofia-Bulgaria; 8, Tsar Kaloyan str.

This declaration of conformity is issued under the sole responsibility of the manufacturer

Declare the following product(s):

Product Type	PPS Safe Care Nitrile Gloves
Ref.Codes Box	Ref.Codes Outer Carton
PPS-SC-01	PPS-SC-06
PPS-SC-02	PPS-SC-07
PPS-SC-03	PPS-SC-08
PPS-SC-04	PPS-SC-09
PPS-SC-05	PPS-SC-10

Compliant

EC Reg. 1935/2004 on materials and articles intended to come into contact with food
Regulation EU N. 10/2011 on plastic materials and articles intended to come into contact with food
The authentic versions of the relevant acts, including all subsequent amendments and additions
including their preambles, are those published in the Official Journal of the European Union
and available in EUR-Lex
<https://eur-lex.europa.eu/eli/reg/2011/10/>

**The company declares the technological suitability of the product for the purpose
for which it is intended**

The limits based on data held by the company, relating global migration test(s) together with the other specific restrictions to which the substances present in the material may be subjected, are complied with under the intended use conditions. The user of the material intended for contact with food is responsible for informing the writing company of any restrictions. We declare that the composition of the above product complies with the relevant requirements of Article 3 of the above regulation 1935/2004 and that the end-use restrictions are met under normal conditions of use. Regarding the traceability of the raw materials used, we can state that there is a system that allows the control of the flow of material in our production and the reference to the materials used by our upstream suppliers according to GMP good manufacturing practice of EC reg 2023/2006

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Applied standards UNI EN 1186-1: 2003 + UNI EN 1186-5:2003

Absence of holes according to ASTM D5151-19
Dimensions and sizes ASTM D3767-03(2020)
Physical properties according to ASTM D412-16 (2021)
Physical properties verification tests after accelerated aging according to ASTM D573-04 (2019)
Absence of dust according to ASTM D6124-06 (2017)
Verification of protein presence in aqueous extract according to ASTM D5712-15 (2020)
Verification of the presence of protein antigens according to ASTM D6499-18

Documents available by ARTEA accredited Italian lab N° 1586 L

Certificate of Analysis NrG220364.01 of 12/07/2022 issued by Marconcini srl.

For tests to demonstrate compliance with the overall migration limit food simulants shall be chosen as set out in table

Foods covered	Food simulants in which testing shall be performed
all types of food	1. distilled water or water equivalent quality or food simulant A; 2. food simulant B; and 3. food simulant D2

Test to verify the suitability of the plastic material in contact with food according to UNI EN 1186-1: 2003 + UNI EN 1186-5 : 2003 through the use of a cell;

Contact time 1 h; Temperature 40 °C;

H2O Simulant - 3 % Acetic Acid Simulant - 10 % Ethyl Alcohol Simulant

Test to verify the suitability of plastic material in contact with food according to

UNI EN 1186-1: 2003 + UNI EN 1186-5 : 2003 + UNI EN 1186-14: 2003 by using a cell;

Contact time 1 h; Temperature 40 °C;

Fat replacement simulant - Olive Oil

The surface to volume ratio in the cell is conventionally 2 dm² of food contact area to 100 ml of food simulant.

Based on the above result, the Nitrile Powder free glove did meet the overall migration requirement under Commission Regulation (EU) N° 10/2011- "Plastic materials and articles shall not transfer their constituents to foodstuffs in quantities not exceeding 10 milligrams of total constituents released per dm² of food contact surface (mg/dm²) (overall migration limit)"

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Specific migration (SML) of Heavy Metals (in 3% Acetic Acid)

Test	Testing condition	Verification of requirement for Specific Migration Limit (mg/kg)*
1. Aluminium, Al	40° C, 1 hour	<1
2. Barium, Ba	40° C, 1 hour	<1
3. Cobalt, Co	40° C, 1 hour	<0.05
4. Copper, Cu	40° C, 1 hour	<5
5. Iron , Fe	40° C, 1 hour	<48
6. Lithium, Li	40° C, 1 hour	<0.6
7. Manganese, Mn	40° C, 1 hour	<0.6
8. Nickel, Ni	40° C, 1 hour	<0.6
9. Zinc, Zn	40° C, 1 hour	<25

Heavy metals detected
Iron <5 mg/kg
Copper <5 mg/kg
Zinc <5 mg/kg

Based on the above results sample met the specific migration (SML) requirements - migration of metals (Al, Ba, Co, Cu, Fe, Li, Mn, Ni, Zn) into food simulants -

Element (mg/kg of foodstuffs)								
Al	Ba	Co	Cu	FE	Li	Mn	Ni	Zn
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

Bisphenol A (BPA) specific migration value

<10

Signed for and on behalf of: PPS Manufacturing JSC

Place: Sofia-Bulgaria

Date of issue: 21/02/2025

Nome/name: Georgi Petkov
General manager

Signature: _____

Stamp:



Vaatimuksenmukaisuustodistus koskee seuraavia Ki-Sal Oy:n
maahantuomia ja myymiä tuotteita:

Ki-Sal tuotekoodi

KKKLN-PPS

Tuotekuvaus ja toimittajan tuotenumero

Nitriilikäsine sininen L 100kpl/pkt (PPS-SC-04)