EU DECLARATION OF CONFORMITY according to EU Regulation 2016/425 ANNEX IX	Rev. 2 oí 4/10/2022

PPE product

NON-SURGICAL PROTECTION NITRILE GLOVES

PPS GLOVES

PPECATEGORY III

Ñame and address of the manufacturer

ÑAME: PPS Manufacturing JSC

ADDRESS LEGAL SITE: Sofia-Bulgaria; 8, Tsar Kaloyan str.

ADDRESS OPERATIVE SITE'. *Kuklensko Shose, 17 4000 Plovdiv Bulgaria*

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

Object of the declaration

Blue color PPS GLOVES

The object of the declaration described above is in conformity according to

2016/425/EU Personal Protective Equipment Regilation ANNEX IX

References to the relevant harmonised standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:

EN ISO 21420:2020
EN 420:2003+AI:2009
EN 374-I:2016+AI:2018
EN 374-2:2014
EN ISO 374-5:2016
EN 374-4:2013
EN 16523-1:2015 + AI:2018

The notified body (ñame, number) performed the EU type-examination (Module B) and issued the EU type-examination certifícate (reference to that certifícate).

EU type cert. Mod.B issued by RICOTEST (notified body n ° 0498)
Via Tione, 9 37010 - Pastrengo (VR) -ITALY
EU Type Examlnatlon Certifícate n. 956220501 /OE Date: 2022/02/03

C/DEL ESLABON NAVE3 POLG.IND.SANTA ANA
28522 RIVAS-VACIAMADRDI
direccion@grupotristan.es
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EU DECLARATION OF CONFORMITY according to EU Regulation 2016/425 ANNEX IX	Rev. 2 of 4/10/2022

PPE is subject to the conformity assessment procedure (either conformity to type based on internal production control plus supervised product checks at random ¡ntervals (Module C2) or conformity to type based on quality assurance of the production process (Module D)) under surveillance of the notified body (ñame, number)

PPE conformity to type assessment procedure based on internal production control
plus supervised product checks at random intervals (Module C2)
under the supervisión of notified body n ° 0498 RICOTEST Via Tione, 9 37010 - Pastrengo (VR)
according the notified body rules as written into the mod.B certifícate the certifícate shall be reconfirmed by the annual surveillance (module C2*) *evidence of first annual surveillance/reconfirmation must/will be available not before the date of 3/2/2023

Signed for and on behalf of: PPS Manufacturing JSC

ADDRESS LEGAL SITE: Sofia-Bulgaria; 8, Tsar Kaloyan.sU,

ADDRESS OPERATIVE SITE: *Kuklensko Shose. 17 4000 Plovdiv Bulgaria*

Stamp:

PPS Manufacturing JSC BULGARIA

Place Sofia-Bulgaria

Date of issue: 4/10/2022

Nome/*name: Georgi Petkov*

General manager

Signature_____

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EU DECLARATION OF CONFORMITY according to EU Regulation 2017/745 ANNEX IV	Rev. 3 of 4/10/2022

Ñame, registered trade ñame or registered trade mark and, if already issued, SRN

as referred to in Article 31 of the manufacturer

ÑAME: PPS Manufacturing JSC

ADDRESS LEGAL SITE: Sofia-Bulgaria; 8, Tsar Kaloyan str.

ADDRESS OPERATIVE SITE* *Kuklensko Shose, 17 4000 Plovdiv Bulgaria*

Actor ID/SRN BG-MF-000026135

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

The Basic UDI-DI as referred to in Part C of Annex VI

Identification code	00380PPSGLOVESVA

Product

NITRILE GLOVES

PPS GLOVES

Risk class of the device in accordance with the rules set out in Annex VIII

Class I medical device

The device that is covered by the present declaration is in conformity with this

Regulation 2017/745 ANNEX IV *of the European Parliament and ofthe Council of 5 April 2017 relating to medical devices as well as REGULA TION (EU) 2020/561 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 April 2020 amending regulation (EU) 2017/745 relating to medical devices. as regards the dates of application of some ofits provisions)*

and with any other relevant Union legislation

regulation (EU) 2016/425 on personal protective equipment

Object ofthe declaration

Blue color PPS GLOVES

References to any CS used and in relation to which conformity is declared

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EU DECLARATION OF CONFORMITY according to EU Regularon 2017/745 ANNEX IV	Rev. 3 of 4/10/2022

Applied HARMONIZED STD(S)

EN 455-1 / 2/3/4 Disposable medical gloves - Requirements and tests

Test report(s)

issued by

laboratorio accreditato*/by accredited italian lab.* N° 1713L

Italian Ministry of Health
BD/RDM database registraron n° 2248561

Classification EMDN

T01020204 - NITRILE EXAMINATION / TREATMENT GLOVES

Signed for and on behalf of: PPS Manufacturing JSC

ADDRESS LEGAL SITE: Sofia-Bulgaria; 8, Tsar Kaloyan str.

ADDRESS OPERATIVE SITE: *Kuklensko Shose. 17 4000 Plovdiv Bulgaria*

Stamp:

PPS Manufacturing JSC BULGARIA

Place Sofia-Bulgaria

Date of issue: 4/10/2022

Nome/*name: Georgi Petkov*

General manager

Signature

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DICHIARAZIONE DI CONFORMITA' MOCAp/ FOOD CONTACT ***CONFORMITY DECLARATION*** In accordo a UNI CEI EN ISO/IEC 17050-1:2010 Valutazione della conformitá - Dichiarazione di conformitá rilasciata dal fornitore - Parte 1: Requisiti general! *According to according to ISO/IEC 17050-1* *Conformity assessment - Supplier's declaration ofeonformity General requirement*	Del/Of	Rev.
	ANNO 2022 YEAR 2022	06

Ragione sociale/*legal site*
8, Tsar Ka/oyan str./yn. LJap
Kanomr, 8, em.2 1000
Ccxpua, Bbmapua
Sofia Bulgaria

Sede operativa/
Operative site
Kuklensko Shose. 17 4000
Plovdiv Bulgaria

PPS
M A NUFACTURINC

PPS Manufacturing JSC

dichiara il seguente prodotto / *declare the following product(s)*

TIPO DI PRODOTTO *PRODUCT TYPE*	GUANTI IN NITRILE **NITRILE GLOVES**
MODELLO/A1ODEL	**PPS GLOVES**

Conforme/ *compliant*

Regolamento CE 1935/2004 relative ai materiali e prodotti destinati ad entrare in contatto con alimenti
EC reg. 1935/2004 on materials and articles intended to come into contact with food
Reg. (UE) N. 10/2011 riguardante i materiali e gli oggetti di materia plástica destinati a venire a contatto con i prodotti alimentan
REGULATION (EU) No 10/2011 on plástic materials and articles intended to come into contact with food
Le versioni autentiche degli atti rilevanti, comprese tutte le successive modifiche e integrazioni compresi i preamboli, sono quelli pubblicati nella Gazzetta Ufficiale dell'Unione Europea e disponibili in EUR-Lex
https://eur-lex. europa. eu/eli/reo/2011/10/

Modifícalo da:

		Gazzetta tificiale		
		n.	pag.	data
▶ MI	Reuolamcnto di csccuzionc (UE) n. 321 / 2011 della Commissione del l" aprile 2011	L 87	1	2.4.2011
▶ M2	Regolamento (UE) n. 1282/2011 della Commissione del 28 novembre 2011	L 328	22	10.12.2011
▶ M3	Regolamento (UE) n. 1183/2012 della Commissione del 30 novembre 2012	l. 338	11	12.12.2012
▶ M4	Regolamento (UE) n. 202 2014 della Commissione del 3 inar/o 2014	1. 62	13	4.3.2014
▶ M5	Regolamento (UE) n. 865/2014 della Commissione dell'K agosto 2014	L 238	1	9.8.2014
▶ M6	Regolamento (UE) 2015/174 della Commissione del 5 febbraio 2015	L 30	2	6.2.2015
▶ M7	Regolamento (UE) 2016'1416 della Commissione del 24 agosto 2016	L 230	22	25.8.2016
▶ M8	Regolamento (UE) 2017/752 della Commissione del 28 aprile 2017	I 113	18	29.4.2017
▶ M9	Regolamento (UE) 2018/79 della Commissione del 18 gennaio 2018	L 14	31	19.1.2018
▶ MIO	Regolamento (UE) 2018213 della Commissione del 12 febbraio 2018	L 41	6	14.2.2018
▶ Mil	Regolamento (UE) 2018-831 della Commissione del 5 giugno 2018	L 140	35	6.6.2018
▶ M12	Regolamento (UE) 2019/37 della Commissione del 10 gennaio 2019	L 9	88	11.1.2019
▶ MI3	Regolamento (UE) 2019 988 della Commissione del 17 giugno 2019	l. 160	10	18.6.2019
▶ M14	Regolamento (UE) 2019/1338 della Commissione dell'K agosto 2019	1. 209	5	9 8.2019
▶ MIS	Regolamento (UE) 2020 1245 della Commissione del 2 setiembre 2020	l. 288	1	3.9.2020

Reí ti liento da:

▶ __	C1	Rettifica. GU I. 278 del 25.10.2011, pag. 13 (10/2011)
▶ __	C2	Rcltiíica. GU L 309 del 19.11.2013. pag. 56 (10/2011)

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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/rea/2011/10/

Amended by:

		Official Journal		
		No	page	date
▶ M1	Coinmission Implemcnting Regulation (EU) No 32I/2O11 of 1 April 2011	L 87	1	2.4.2011
▶ M2	Coinmission Regulation (EU) No 1282/20H of 28 November 2011	L 328	22	10.12.2011
▶ M3	Coinmission Regulation (EU) No H83/2012 of 30 November 2012	E 338	11	12.12.2012
▶ M4	Coinmission Regulation (EU) No 202/2014 of 3 Mareh 2014	L 62	13	4.3.2014
▶ M5	Coinmission Regulation (EU) No <865/2014 of 8 August 2014	L 238	1	9.8.2014
▶ M6	Coinmission Regulation (EU) 2015/174 of 5 1 ebniary 2015	1. 30	2	6.2.2015
▶ M7	Coinmission Regulation (EU) 2016/1416 of 24 August 2016	L 230	22	25.8.2016
▶ M8	Coinmission Regulation (El[1]) 2017/752 of 28 April 2017	L 113	18	29.4.2017
▶ M9	Coinmission Regulation (EU) 2018/79 of 18 January 2018	I. 14	31	19.1.2018
▶ MIO	Coinmission Regulation (EU) 2018/213 of 12 February 2018	E 41	6	14.2.2018
▶ Mil	Coinmission Regulation (EU) 2018/831 of 5 June 2018	L 140	35	6.6.2018
▶ M12	Coinmission Regulation (EU) 2019/37 of 10 January 2019	E 9	88	II.1.2019
▶ M13	Coinmission Regulation (EU) 2019/988 of 17 June 2019	I. 160	10	18.6.2019
▶ M14	Coinmission Regulation (EU) 2019/1338 of 8 August 2019	I 209	5	9.8.2019
▶ M15	Coinmission Regulation (EU) 2020/1245 of 2 September 2020	L 288	1	3.9.2020

Corree ted by:

▶ C£ Corrigendum, OJ L 349, 19.12.2012, p. 77 (1183/2012)

L'azienda dichiara l'idonèita tecnológica del manufatto alio scopo cui é destinato

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

I limiti basati sui dati in possesso dell'azienda sono basati su prove di migrazione globale, unitamente alie altre restrizioni specifiche alie quali possono essere sottoposte le sostanze presentí nel materiale, sono rispettati nelle condizioni d'uso previste. L'utilizzatore del materiale destinato al contatto con gli alimenti ha la responsabilitá di comunicare alia societá scrivente eventuali. Dichiariamo che la composizione del prodotto di cui sopra é conforme ai requisiti pertinenti dell'articolo 3 del regolamento 1935/2004 di cui sopra, e che le restrizioni per l'uso finale sono soddisfatte in condizioni d'uso normali. Per quanto riguarda la tracciabilitá delle materie prime utilizzate, possiamo affermare che esiste un sistema che consente il contrallo del flusso di materiale nella nostra produzione e il riferimento ai materiali utilizzati dai nostri fomitori a monte secondo le buone pratiche di fabbricazione come al reg. CE 2023/2006

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 ofthe material intended for contad with food is responsible for informing the writing company of any restrictions. We *declare that the composition ofthe above product complies with the relevant requirements ofArticle 3 ofthe above regulation 1935/2004 , and that the end-use restrictions are met under normal conditions of use. Regarding the traceability ofthe raw materials used, we can State that there is a system that allows the control ofthe flow of material in our production and the reference to the materials used by our upstream suppliers according to GMP good manufacturing practice ofEC reg. 2023/2006*

Norme applicate/*applied standard(s)*

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

ASTM D7329-07 (2018)	
Assenza di fori secondo ASTM D5151-19	*Absence ofholes according to ASTM D5151-19*
Dimensioni e taqlie ASTM D3767-03 (2020)	*Dimensions and sizes ASTM D3767-03 (2020*
Proprietá fisiche secondo ASTM D412-16 (2021)	*Physical properties according to ASTM D412-16 (2021)*
Prove di verifica proprietá fisiche dopo invecchiamento accelerato secondo ASTM D573-04 (2019)	*Physical properties verification tests after accelerated aging according to ASTM D573-04 (2019)*
Assenza di polvere secondo ASTM D6124-06 (2017)	*Absence of dust according to ASTM D6124-06 (2017)*
Verifica presenza proteica in estratto acquoso secondo ASTM D5712-15 (2020)	*Verification of protein presence in aqueous extract according to ASTM D5712-15 (2020)*
Verifica di presenza di antigeni proteici secondo ASTM D6499-18	*Verification ofthe presence of protein antigens according to ASTMD6499-18*

Documenti disponibili/ *documents available*

Rapporto di prova n° 1_11/01/22 del 11/01/2022
Da laboratorio italiano ARTEA accreditato con n° 1586 L
Test report n' 1_11/01/22 of 11/01/2022
By ARTEA accredited ¡tallan lab. N° 1586 I
Certificato d'analisi / certificate of analysis nr. G220364.01 del/of 12/07/2022 emesso da / issued by Marconcini sri

I18C-MRA

ACCREDIA

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Per le prove volte a dimostrare il rispetto del limite di migrazione globalo, i simulanti alimentan devono essere scelti come indicato
For tests to demónstrate compliance with the overall migration limit food simulants shall be chosen as set out in table

Selezione di simulanti alimentán per prodotti destinati a contatto con "tutti i tipi di alimenti" in generale simulanti alimentan A, B, D2

A: etanolo 10 % (v/v) (simulante alimentare A) - [A0BA8]
B: acido acético 3% (P/v) (Simulante alimentare B) - [AOBAF]
D2: olio vegetale (simulante alternativo utilizzato: isottano)

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

Prova di verifica idoneitá del materiale plástico a contatto con gli alimenti secondo la norma UNI EN 1186-1:2003 + UNI EN 1186-5:2003 mediante l'utilizzo di una celia;
Tempo di contatto 1 h; Temperatura 40°C;
Simulante H2O - Simulante Acido Acético al 3% - Simulante Alccol Etílico al 10%
Prova di verifica idoneitá del materiale plástico a contatto con gli alimenti secondo la norma UNI EN 1186-1:2003 + UNI EN 1186-5:2003 + UNI EN 1186-14:2003 mediante l'utilizzo di una celia;
Tempo di contatto 1 h; Temperatura 40°C;
Simulante sostitutivo di grassi - Olio d'oliva

Test to verify the suitability of the plástic material in contad with food according to UNI EN 1186-1: 2003 + UNI EN 1186-5: 2003 through the use of a cell;
Contad time 1 h; Temperature 40 ° C;
H2O Simulant - 3% Acetic Acid Simulant - 10% Ethyl Alcohol Simulant
Test to verify the suitability of plástic material in contad 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

Il rapporto superficie/volume nella celia é convenzionalmente di 2 dm^2 di area di contatto con gli alimenti per 100 mi di simulante alimentare.
The surface to volume ratio in the cell is conventionally 2 dm^2 of food contact area to 100 mi offood simulant.

Based on the above result the Nitrile Powder free glove did met the overall migration requirement under Commission Regulation (EU) No. 10/2011- "Plástic materials and articles shall not transfer their constituents to foodstuffs in quantities not exceedmg 10 milligrams of total constituents released per dm^2 of food contact surface (mg/drrr)' (overall migration limit)'

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Limiti di migrazione specifica (SML)
di metallic pesanti (in 3% Acético Acido)
Specific Migration (SML)
of Heavy Metals (in 3% Acetic Acid)

ITA

Test	Condiziono	Verifica di requlsiti pcrSpecifIco Migrazione Limite (mg/kg)*
1. Allumlnio, AJ	40'C, lora	<1
2. *Bario*, Ba	40'C, lora	<1
3. Cobalto, co	40'C, lora	<0,05
4. Rame, Cu	40'C, lora	<S
5. Ferro, Fe	40'C, lora	<48
6. Litio. U	40'C, lora	<0,6
7. Manganese, Mn	40'C. lora	<0,6
8. Nickel. Ni	40 'C, 1 ora	<0.5
9. Zinco, Zn	40'C, lora	<25

ENG

Test	Testing Condition	Verification of requirement for Specific Migration LImit (mg/kg)*
1. Aluminum, 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

Metalli pesanti rilevati /heavy metáis detected
Ferro/Iron <5 mg/kg
Rame/Copper <5 mg/kg
Zinco/Zinc <5 mg/kg

Basandosi sui risultati, sono soddisfatti I limiti di migrazione specifica (SML) di metallic pesanti (Al, Ba, Co, Cu, Fe, Li, Mn, Ni, Zn) in simulanti alimentan.

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

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

Valore di migrazione specifica (SML) (Bisphenol A) (BPA) / *(BisphenolA) (BPA) specific migration valué*

<10 pg/Kg

Non sono stati utilizzati additivi a duplice uso (DUA) per produrre guanti in nitrile PPS
No dual-use additives (DUA) were used to produce PPS nitrile gloves

Conclusione: i guanti sono adatti per essere utilizzati con tutti i tipi di alimenti
Conclusión: gloves are suitable to be used with all types offood

There are no known substances subject to purity criterio.
There are no known substances subject to restríctions
Time and temperature and storage while in contad with the food:
máximum temperature of40°C up to lh.

19/9/2022	Plovdiv	Georgi Petkov
Luogo/p/ace	Data/date	Amministratore/genera/ *manager*

company stamp and signature

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