

**Name, registered trade name or registered trade mark and, if already issued, SRN
as referred to in Article 31 of the manufacturer**



NAME: 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 sole responsibility of the manufacturer

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

<i>identification code</i>	00380PPSGLOVESVA
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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 of the Council of 5 April 2017 relating to medical devices
as well as REGULATION (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 of its provisions)*

and with any other relevant Union legislation
regulation (EU) 2016/425 on personal protective equipment

Object of the declaration

Blue and black color PPS GLOVES

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

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 registration 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:



Place Sofia-Bulgaria

Date of issue: 25/10/2022

Nome/name: *Georgi Petkov*

General manager

Signature

A handwritten signature in blue ink, consisting of several loops and a long horizontal stroke, written over a horizontal line.