

**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

**Brand**

SAINA

**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 color gloves - brand SAINA

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:** 2/10/2023

**Nome/name:** *Dimitar Stamov*

*General manager*

**Signature** \_\_\_\_\_

A handwritten signature in blue ink, consisting of a series of loops and a long vertical stroke, positioned to the right of the signature line.