

# EU DECLARATION OF CONFORMITY



**Textiles at work**

www.polishtextilegroup.com  
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POLSKA GRUPA TEKSTYLNA  
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NIP PL 552-270-98-59  
REGON 015633446

1. Name, registered trade name or registered trade mark and, if already issued, SRN as referred to in Article 31 of the manufacturer, and, if applicable, its authorised representative, and the address of their registered place of business where they can be contacted and their location be established

2. A statement that the EU declaration of conformity is issued under the sole responsibility of the manufacturer;

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

4. Product and trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device covered by the EU declaration of conformity, such as a photograph, where appropriate, as well as its intended purpose. Except for the product or trade name, the information allowing identification and traceability may be provided by the Basic UDI-DI referred to in point 3;

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

6. A statement that the device that is covered by the present declaration is in conformity with this Regulation and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity;

Polska Grupa Tekstylna Sp. z o.o.  
address: ul. Zeusa 27, 01 – 497 Warszawa (PGT  
Sp. z o.o./Manufacturer)

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Not applicable

LDNG Nitrile examination gloves, medical, disposable, powder-free, non-sterile, ambidextrous



Class I medical device

Personal Protective Equipment; category I

A class I medical device to which this EU declaration of Conformity applies, which is also a Personal Protective Equipment of category I, complies with:

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83 / EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385 / EEC and 93/42 / EEC (OJ EU L.2017.117.1 of 2017.05.05),
- Council Directive 93/42 / EEC of June 14, 1993 on medical devices (Journal of Laws UE L 1993, 169.1 of 1993.07.12), Ustawą z dnia 10.05.2010 r. o wyrobach medycznych (t.j.: Dz.U. z 2020 r. poz. 186),
- Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment (Journal of Laws EU L.2016.81.51 of 2016.03.31).



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

- EN 455-1: 2000; Disposable medical gloves. Part 1. Requirements and testing for the presence of holes;
- EN 455-2: 2015; Disposable medical gloves. Part 1. Requirements and tests for physical properties
- EN 374-1: 2016; Gloves protecting against hazardous chemicals and microorganisms
- EN 420: 2003 + A1: 2009 Protective gloves. General requirements and test methods.

Not applicable

8. Where applicable, the name and identification number of the notified body, a description of the conformity assessment procedure performed and identification of the certificate or certificates issued;

Not applicable

9. Where applicable, additional information;

10. Place and date of issue of the declaration, name and function of the person who signed it as well as an indication for, and on behalf of whom, that person signed, signature.:

Warszawa, 25.01.2021

On behalf of PGT Sp. z o.o.:

signature

Name: Paweł Gałazka

Position: Member of the Board

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