

EU DECLARATION OF CONFORMITY

EFFECT PF BLUE

nitrile examination and protective gloves, powder-free, blue, disposable, box a'100

Sizes: XS- XL

R-N-B-EF100-XS, R-N-B-EF100-S, R-N-B-EF100-M R-N-B-EF100-L, R-N-B-EF100-XL

Manufacturer:

SAFEMED Gil, Bluszcz Spółka Jawna
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We declare under our sole responsibility that the product is classified as **Medical Device** class I, rule 4, in accordance with Annex VIII of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5th April 2017 on medical devices.

The device covered by this Declaration complies with European standards:
EN 455-1, EN 455-2, EN 455-3, EN 455-4, EN 1041, EN ISO 14971, EN ISO 15223-1.

Code Basic UDI-DI: 5907675510RNEFFEQ

The device covered by this declaration is compliant with the provisions of Regulation (EU) 2016/425 of the European Parliament and of the Council of 9th March 2016 on Personal Protective Equipment and repealing Council Directive 89/686/EEC as **Personal Protective Equipment** of category III.

The device is also compliant with European standards:
EN 420:2003+A1:2009, EN ISO 374-1:2016, EN ISO 374-5:2016, EN 374-2:2015, EN 374-4:2013, EN 16523-1:2015.

The detailed list of applied standards is included in the device technical documentation no. DT-05.

The notified body SATRA Technology Europe Limited (2777) performed the EU-type examination (Module B) and issued the EU-type examination certificate no.: 2777/11521-01/E03-01.

PPE is subject to conformity to type assessment procedure based on internal production control and supervised product checks at random intervals (Module C2) under surveillance of the notified body SATRA Technology Europe Limited (2777).

Place and date of issue:

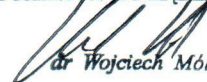
Kraków, 27.05.2021

Signed for and of behalf of Manufacturer:

Wojciech Mól
Managing Director

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DYREKTOR ZARZADZAJĄCY



Dr. Wojciech Mól