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-BEF100-XS, R-N-B-BEF100-S, R-N-B-BEF100-M R-N-B-BEF100-L, R-N-B-BEF100-XL

Manufacturer:
SAFEMED Spółka z ograniczoną odpowiedzialnością
Ul. Strefowa 22, 43-100 Tychy
Polska/Poland
tel. +48 12 681 42 52
email: biuro@safemed.pl
SRN: PL-MF-000039365

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 ISO 20417, 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 ISO 21420:2020, EN ISO 374-1:2016+A1:2018, EN ISO 374-5:2016.

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.: 2777/21028-03/E14-02.

PPE is subject to conformity to type assessment procedure based on quality assurance of the production process (Module D) under surveillance of the notified body SATRA Technology Europe Limited (2777).

Place and date of issue:

Tychy 16.09.2024

Signed for and of behalf of Manufacturer:

Wojciech Mól
Managing Director

DYREKTOR ZARZĄDU
dr Wojciech M...