

EU Declaration of Conformity according to the Medical Devices Regulation (EU) 2017/745 and the PPE Regulation (EU) 2016/425

The manufacturer:

MED COMFORT d.o.o.
Dobojska 38A
10000 Zagreb
Hrvatska

declares under its own responsibility that

Art. No. 970-024 XS-XL PROTECT BLUE Nitrile Gloves

- 1) Complies with the requirements of Annex VII of Regulation (EU) 2017/745 and the harmonised standards; EN 455-1:2020, EN 455-2:2015, EN 455-3:2015 and EN 455-4:2009.

This product is a Class I medical device according to the classification in Annex IX.

and

- 2) complies with the requirements of regulation (EU) 2016/425 and the harmonized standards of EN ISO 374-1:2016 (Type B), EN ISO 374-5:2016, EN 420:2003+A1:2009 and the standard EN 374-4:2013

This product is a PPE of category 3 in accordance with attachment I of the regulation and is identical with that PPE which was subject to the EU type examination certificate No. 2777/120001/E11-01 issued by the Satra identification number 2777 and that is subject to the procedure according to Modul C2 of the regulation (EU) 2016/425 under the control of the notified body Satra (2777 identification number).

Technical documentation is available to prove this is accordance with the requirements.

Zagreb, 13.08.2020

MED-COMFORT
d.o.o.
ZAGREB 1

Danica Bosnjak
Director

This Declaration of Conformity is valid until 21.02.2024