

Declaration of Compliance

We distributor, WIMEX s.r.o.
 Broumovska 72
 CZ-54701 Náchod

hereby declare that the following products comply with:

- REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices
- REGULATION (EU) 2016/425 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2016 on personal protective equipment

WIMEX art.no	Article description	Material type
68120	Glove (Vinyl) powdered white `S` [100 pcs]	Vinyl
68121	Glove (Vinyl) powdered white `M` [100 pcs]	Vinyl
68122	Glove (Vinyl) powdered white `L` [100 pcs]	Vinyl
68123	Glove (Vinyl) powdered white `XL` [100 pcs]	Vinyl
68125	Glove (Vinyl) powder-free white `S` [100 pcs]	Vinyl
68126	Glove (Vinyl) powder-free white `M` [100 pcs]	Vinyl
68127	Glove (Vinyl) powder-free white `L` [100 pcs]	Vinyl
68128	Glove (Vinyl) powder-free white `XL` [100 pcs]	Vinyl
68128	Glove (Vinyl) powder-free white `XL` [100 pcs]	Vinyl

And they comply with the following standards:

EU Directive	EU standard
MDR Class I – non sterile	EN ISO 374-1:2016 EN 374-2:2014 EN 374-4:2013 EN ISO 374-5:2016 EN 420:2003+A1:2009 EN 455-1:2000 EN 455-2:2015 EN 455-3:2015 EN 455-4:2009 EN ISO 13485:2016 EN 16523-1:2015
PPE Category III	EN ISO 374-1:2016+A1:2018 Type C EN 374-4:2019 EN 374-5:2016 Bacteria, Fungi, Virus EN ISO 21420:2020

EU Type Examination Module B performed by notified body 2777 SATRA Technology Europe Limited, Bracetown Business Park, Clonee, D15YN2P Ireland and issued the EU Type Examination certificate 277/17971-02/E03-01.

