

Date: 16th May'2022

EC- Declaration of conformity for Medical Device Regulation (EU) 2017/745 and
Personal Protective Equipment Regulation (EU) 2016/425

We, at Innovative Gloves Company Limited herewith declare and issue this EC-declaration of conformity is under our sole responsibility that the Nitrile polymer coated Gripper textured 7 mil Orange color disposable Gloves supplied by us to our customer KEYPOINT UK are meeting all the applicable provisions, especially the essential requirements of the EU Regulations and standards.

The applicable EU Regulations and standards are

- 1) MDR (EU) 2017/745. The required conformity assessment procedure according to MDR Annex II & III has been performed and the technical documentation is kept available.
- 2) PPE Regulation (EU) 2016/425 of the European parliament and of the council on PPE Category III. The required conformity assessment procedure according to PPE regulation has been performed and the technical documentation is kept available.

Medical Device: Class 1 according to Rule 1 and 5 according to MDR Annex VIII.

EMDN: T01020204

UMDNS: 11882

GMDN: 56286

EC Representative for our Innovative gloves Company Limited is
Advena Limited, Tower business centre, 2nd Floor Tower Street,
Swatar, BKR 4013, Malta. (SRN No.: MT-AR-000000234)

This Declaration of Conformity is issued on the basis of fulfilment the requirements of Annex IV of the Medical Device Regulation (EU) 2017/745 with:

- Quality Management System certification to EN ISO 13485: 2016 under the supervision of TÜV SÜD America Inc., certificate no. QS2 086222 0005 Rev.01

For PPE regulation: The object of the declaration is in conformity with the following relevant union harmonization legislation:

- EN ISO 21420:2020, EN 420:2003+A1:2009
- EN 455-1:2020, EN 455- 2&3:2015, EN 455- 4:2009
- EN ISO 374-1:2016 + A1:2018
- EN ISO 374-2:2014
- EN 16523-1:2015
- EN ISO 374-4:2013
- EN ISO 374-5:2016

And compliance to ASTM D6319, ASTM D 5151 and ASTM D412 standards, Food Safe Application — Over All Migration EN 1186, EU Reg. 10/2011, EU Reg. 1935/2004 and US FDA 21 CFR 177.2600 (e) & (f).

Compliance to REACH 1907/2006: SVHC - Annex XIV and Annex XVII. The raw materials used in our process are non-hazardous and the MSDS are duly updated as necessary.

Our notified Body (N.B no.2777) is SATRA Technology Europe Ltd., Bracetown, Business park, Clonee, D15YN2P, Ireland and it is performing the ongoing EU type-examinations (Module C-2), issued the Module C2 and the EU type CAT III examination certificate: 2777/11537-03/E00-00 for Nitrile Gripper texture gloves in Orange, Black, Blue and Red colors.

 16/5/22

(V.SARAVANAKUMAR)
Sr. Manager - Technical
Authorized Signatory
Innovative Gloves Company Limited

Validity of this Declaration until: 24/01/2026