

## **Declaration of Conformity**

Manufacturer: TraffiSafe Ltd

Manufacturer's Address: Innovation House, Unit 18 Caker Stream Road,

Mill Lane Industrial Estate, Alton, Hampshire, GU34 2QA, UK.

EU Authorised Representative: TraffiSafe Europe Srl,

Via Colle Fiorito 2, Genzano di Roma, 00045 (RM), Italy

Product Brand: Traff

**Product Description:** Powderfree ambidextrous Nitrile Rubber gloves available in Blue

which are available in four sizes

Product Code: TD01
Size range: XS-XXL
PPE Category: Category III
Medical Device Category: Class I

## It is declared that the above product:

• is in conformity with the provisions of Regulation (EU) 2016/425 on personal protective equipment and with National Standards transposing harmonised standards and as amended to apply in GB. EN 455-1:2000, EN 455-2:2015 & EN 455-3:2015

EN ISO 374-1:2016+A1:2018 Type B, EN ISO 374-4:2019 Degradation % EN ISO 374-5:2016

40% Sodium Hydroxide (K) - Level 6 -63.12 Protection against bacteria & fungi - Pass

25% Ammonia Hydroxide (O) - Level 6 -7.55 Protection against viruses - Pass

37% Formaldehyde (T) - Level 4 -20.6

EN ISO 374-2:2019, Food Contact Regulation (EU)1935:2014 - EN1186 and EN ISO 21420:2020.

• is identical to the personal protective equipment which is the subject of EU Type-Examination

## Certificate number 2777/14376-03/E01-02,

issued by SATRA Technology Europe Limited, Bracetown Business Park, Clonee, Dublin, D15 YN2P, Republic of Ireland (**Notified Body number 2777**), according to Annex V (Module B) of Regulation (EU) 2016/425.

 is subject to the conformity assessment procedure Module C2 set out in Annex VII of Regulation (EU) 2016/425, under the surveillance of the notified body SATRA Technology Europe Limited, Bracetown Business Park, Clonee, Dublin, D15 YN2P, Republic of Ireland (Notified Body number 2777). • is in conformity with the provisions of Council Directive 93/42/EEC on medical devices and with National Standards transposing harmonised standards EN 455-1:2000, EN 455-2:2015, EN 455-3:2015, and is self-certified as a Class 1 non-sterile medical device (according to Annex IX rule 5).

On behalf of TraffiSafe Ltd

Agrane

Adrian James Managing Director



Ref No: TD01/Doc/24