

## **Declaration of Conformity**

Manufacturer: Manufacturer's Address:	TraffiSafe Ltd 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:	Traffi
Product Description:	Biodegradable Nitrile powder free disposable 4.5mil glove
	textured palm and fingers
Product Code:	TD04
Size range:	S-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
  EN ISO 374-1:2016+A1:2018,
  EN ISO 374-5:2016
  BS EN 16523-1:2015 + A1:2018
  and EN ISO 21420:2020.
  Food approved EN 1186 / Regulation EU 10/2011
- is identical to the personal protective equipment which is the subject of EU Type-Examination

## Certificate number 2777/20616-02/E01-01,

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.

On behalf of TraffiSafe Ltd

Adrian James Managing Director

- 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).

