

Declaration of Conformity

Manufacturer:	TraffiSafe Ltd
Manufacturer's Address:	Venture Park, Selborne Road, Alton, Hampshire, GU34 3HL UK.
Product Brand:	Traffi
Product Description:	Blue Nitrile examination powder free disposable glove
Product Code:	TD01 (NE002)
Size range:	S-XL
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 2777/14376-02/E00-00,
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



Adrian James Managing Director

