

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. |
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| 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: | 7(S)-10(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 2777/20616-01/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).





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Product Brand: Product Description:

Product Code:

Size range:

TraffiSafe Ltd Innovation House, Unit 18 Caker Stream Road, Mill Lane Industrial Estate, Alton, Hampshire, GU34 2QA, UK. Traffi Biodegradable Nitrile powder free disposable 4.5mil glove textured palm and fingers **TD04** 7(S)-10(XL) Category III Class I

PPE Category: Medical Device Category:

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 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

The product is subject of UKCA Type examination (Module B) and Module C2 ongoing Conformity under

certificate No: AB0321/20855-01/E01-01

issued by approved body:

SATRA Technology Centre Limited, (Approved Body number 0321)

Wyndham Way, Telford Way, Kettering, Northamptonshire. NN16 8SD. United Kingdom

On behalf of TraffiSafe Ltd

Adrian James Managing Director





Ref No: TD04/Doc/23

Issue Date: 07/06/2022