Declaration of Conformity

Ultra*TOUCH* Nitrile Gloves

Product name	Ultra*TOUCH* Nitrile Gloves
Product codes	1020, 1021, 1022, 1023, 1024, 1025
Available sizes	Extra Small, Small, Medium, Large, Extra large
Manufacturer	PRO Hygiene Products
Manufacturer address	PO Box 168, BRISTOL, BS31 9EE, UK

1. This declaration of conformity is issued under the sole responsibility of the manufacturer.
2. Object of the declaration: PRO Ultra*TOUCH* Nitrile Gloves
3. Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) – UKCA
    a. In compliance with Medical Devices Regulations 2002 (SI 2002 No. 618, as amended) (UK MDR 2002).
    b. This product is classified under Class I Medical Device per Rule 1 and Rule 5 of Annex IX, meets the provisions of the Council Directive 93/42/EEC, as amended by the Council Directive 2007/47/EC.
    c. This product complies with Designated Standards BS EN 455-1:2020, BS EN 455-2:2015, BS EN 455-3:2015, and BS EN 455-4:2009.
4. PPE EU Type-Examination
    a. This product is classified as Category III Personal Protective Equipment (PPE) according to PPE Regulation (EU) 2016/425 as retained in UK Law and amended and has been shown to comply with this Regulation through the Designated Standards BS EN ISO 21420:2020, BS EN ISO 374- 1:2016+A1:2018 and BS EN ISO 374-5:2016.
    b. UK Approved Body responsible for certification and Module B compliance is SATRA Technology Centre Ltd (AB0321), Wyndham Way, Kettering NN16 8SD, United Kingdom.
    c. UK Approved Body responsible for internal production control plus supervised product checks at random intervals is SATRA Technology Centre Ltd (AB0321), Wyndham Way, Kettering NN16 8SD, United Kingdom.

Signed for and on behalf of	PRO Hygiene Products
Place of issue	Bristol
Date of issue	21 April 2023
Name	Richard Wilson
Position	Director

Signature: R Wilson