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 Device Directive (MDD)
    a. 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.
    b. This product complies with European Standards EN 455-1:2000, EN 455-2:2015, EN 455-3:2015, and EN 455-4:2009.
4. PPE EU Type-Examination
    a. This product is classed as Category III of Personal Protective Equipment (PPE) according to PPE Regulation (EU) 2016/425 and has been shown to comply with this Regulation through the Harmonised European Standards BS EN 420:2003+A1:2009, EN ISO 374-1:2016+A1:2018 and EN ISO 374-5:2016.
    b. Notified Body responsible for certification and Module B compliance is SATRA Technology Europe Limited, 2777, Bracetown Business Park, Clonee, Dublin 15, D15 YN2P, Ireland.
    c. Notify Body responsible for internal production control plus supervised product checks at random intervals (Module C2) is SATRA Technology Europe Limited, 2777, Bracetown Business Park, Clonee, Dublin 15, D15 YN2P, Ireland.

Signed for and on behalf of	PRO Hygiene Products
Place of issue	Bristol
Date of issue	22 August 2019
Name	Simon Hubner
Position	Managing Director

Signature: S. Hubner