Fannin
Caring for Life since 1829

EC Declaration of Conformity

Declaration Number: DC – TF005/PFNT-NS Rev 03

Manufacturer: Fannin Ltd, Fannin House, South County Business Park, Leopardstown Dublin 18
Email: info@fannin.eu
Website: www.fannin.eu

Product	*Basic UDI*
POWDER FREE NITRILE EXAMINATION GLOVES Product No: C1900-00, C1901-24, C1902-24, C1903-24, C1904-24	955 525660 NE PF N LW

is in conformity with the

Medical Device Regulation (EU) 2017/745, under Class I Medical Device per set out in Rule 1 and Rule 5 of Annex VIII, complying with the European standards EN 455-1:2000, EN 455-2:2015, EN 455-3:2015, and EN 455-4:2009.

And

Personal Protective Equipment Regulation (EU) 2016/425, under Category III risk per set out in Annex I, complying with the European standards EN 420:2003+A1:2009, EN ISO 374-1:2016+A1:2018, EN ISO 374-5:2016. It is identical to the PPE which is subject to the EU Type Examination (Module B) under certificate number **2777/10115-02/E06-01** issued by Notified Body:

SATRA Technology Europe Limited (2777)
Bracetown Business Park, Clonee, Dublin 15, D15 YN2P, Ireland

and is subject to the annual conformity assessment procedure which is based on internal production control plus supervised product checks at random intervals (Module C2) under surveillance of the Notified Body:

SATRA Technology Europe Limited (2777)
Bracetown Business Park, Clonee, Dublin 15, D15 YN2P, Ireland

The above-mentioned product demonstrates fulfilment to the essential health and safety requirements set out in Annex II of PPE Regulation (EU) 2016/425.

Issued By:Noinin Reynolds
Head of Regulatory

Signature:

Dated: 14/11/2024