

EU Declaration of Conformity

The manufacturer and authorised representative established in the Union:

Unigloves (UK) Limited	UNIGLOVES® Arzt-und Klinikbedarf Handelsgesellschaft mbH		
3 Ambley Green	Camp-Spich-Str. 71		
Gillingham	53842 Troisdorf		
Kent ME8 0NJ	Germany		
UK	<table border="1"><tr><td>EC</td><td>REP</td></tr></table>	EC	REP
EC	REP		

declare that the PPE and medical devices listed in Annex I are in conformity with;

PPE Regulation (EU) 2016/425 as amended and with harmonised standards EN ISO 374-1:2016, EN ISO 374-5:2016 and EN 420:2003+A1:2009.

SATRA Technology Europe (Notified Body 2777) performed the EU type-examination (Module B) and issued the EU type-examination certificate 2777/10887-04/E00-00.

is subject to the conformity assessment procedure set out in Module C2 of Regulation EU (2016/425) under the supervision of SATRA Technology Europe, Bracetown Business Park, Clonee, D15 YN2P, Ireland (Notified Body 2777)

and

Medical Devices Directive 93/42/EEC as amended and with harmonised standards EN455-1:2000, EN455-2:2015, EN455-3:2015 and EN455-4:2009 and is Class I self-certified.

This declaration of conformity is issued under the sole responsibility of the manufacturer.



Done at Gillingham on 2nd April 2019.

Chris Wahlers
Director
Unigloves (UK) Limited

Annex I

Product Code	Product description
GA004*	PRO.TECT Black
GA005*	PRO-TECT Orange HD
GA006*	PRO-TECT Black HD
GA007*	PRO-TECT Black HD+
GA008*	PRO-TECT Green HD
GA009*	PRO-TECT Green HD+
GD003*	Vitality Nitrile
GD004*	Vitality Soft Nitrile Citrus
GD005*	Vitality Soft Nitrile
GF001*	Fortified Nitrile
GL001*	Paragon+ (EC) Blue Nitrile
GL002*	Unicare Nitrile +
GM004*	Kooltouch Blue Nitrile
GM006*	Stronghold Purple Nitrile
GM007*	Stronghold+
GP001*	Blue Pearl Nitrile
GP002*	White Pearl Nitrile
GP003*	Black Pearl Nitrile
GP004*	Green Pearl Nitrile
GP005*	Pink Pearl Nitrile
GP006*	Red Pearl Nitrile
GP007*	Violet Pearl Nitrile
GP008*	Sapphire Pearl Nitrile
GP009*	Aqua Pearl Nitrile
GP010*	Peach Pearl Nitrile
GP011*	Yellow Pearl Nitrile
GP012*	Burgundy Pearl Nitrile
GP013*	Cobalt Pearl Nitrile
GP014*	Lime Green Pearl Nitrile
GP015*	Magenta Pearl Nitrile
GS003*	Unicare Nitrile
GS004*	Unicare Nitrile (200s)
GT003*	Select Black Nitrile
GU004*	PRO.TECT Blue
GU00A*	Unicare Premium
GV001	Vending Pack Unicare Soft Nitrile
GV003	Vending Pack Paragon+