

# **EU Declaration of Conformity**

 $\bigcap \mathbf{i}$ The manufacturer 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

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, Medical Devices Regulation (EU) 2017/745 as amended (effective from 26/05/2021), and with harmonised standards EN455-1:2000, EN455-2:2015, EN455-3:2015 and EN455-4:2009 and is Class I self-certified.

CE

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

Done at Troisdorf on 11th May 2020.

Sebastian Schuster Geschäftsführer UNIGLOVES® Arzt-und Klinikbedarf Handelsgesellschaft mbH

**Chris Wahlers Managing Director** Unigloves (UK) Limited

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Registered office: 37 St Margaret's Street, Canterbury, Kent, CT1 2TU Registered in England No. 04010200 VAT registration 791817787

### **UNIGLOVES GERMANY**

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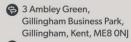
Geschäftsführer: Sebastian Schuster, Robert Feldmeier Handelsregister Siegburg HRB 5002 USt.-ID Nr. DE 122266038 Steuer-Nr. 220/5864/0164



## 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+
GA010*	PRO.TECT Blue XHD+
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
101*	Cobalt Pearl Nitrile
350*	Lime Pearl Nitrile
850*	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+

#### **UNIGLOVES UK**



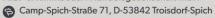
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