

EU Declaration of Conformity



Unigloves (UK) Limited
3 Ambley Green
Gillingham
Kent ME8 0NJ
UK

The manufacturer established in the Union:

UNIGLOVES® Arzt-und Klinikbedarf Handelsgesellschaft mbH
Camp-Spich-Str. 71
53842 Troisdorf
Germany

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.



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

UNIGLOVES UK

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37 St Margaret's Street,
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Registered in England
No. 04010200
VAT registration 791817787

UNIGLOVES GERMANY

Arzt- & Klinikbedarf Handelsgesellschaft mbH
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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+ |

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