

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 2777/12332-01/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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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
GD001*	Vitality Latex Mint
GD002*	Vitality Latex
GM002*	Supergrip Latex
GT001*	Select Black Latex (EC)
GT002*	Select Black Latex

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