EU Declaration of Conformity

UK Responsible Person
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

Basic UDI-DI according to Annex VI Part C
4260503143710R3

Single Registration Number according to Article 31
DE-MF-000013340

We declare that the non-sterile disposable examination gloves covered by this declaration and listed in Annex I, whose intended use is to protect patients, users or third parties against diseases and provide temporary protection against bacteria, fungi, viruses and certain chemicals, can be used in the laboratory, medical and industrial sector as well as in the domestic area by laypersons and health care users, are in conformity as PPE and medical devices with:

PPE Regulation (EU) 2016/425 as amended and with standards EN ISO 374-1:2016+A1:2018, EN ISO 374-5:2016 and EN ISO 21420:2020.

SATRA Technology Europe (Notified Body 2777) performed the EU type-examination (Module B) and issued the EU type-examination certificate 2777/22896-01/E00-00 for category 3 PPE, EN374 Type B

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)

CE 2777

and

Medical Devices Regulation (EU) 2017/745 as amended and with standards EN455-1:2020, EN455-2:2015, EN455-3:2015 and EN455-4:2009 and are Class I self-certified according to Annex VIII, Rule 1 and 5 and are subject to conformity assessment procedure using technical documentation according to Annex II and Annex III

CE

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

Done at Troisdorf on 26 April 2024.

Sebastian Schuster
Managing Director
UNIGLOVES® Arzt-und Klinikbedarf Handelsgesellschaft mbH

UK Declaration of Conformity

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

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

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

UK PPE Regulation 2016/425 as amended and with UK designated standards EN ISO 374-1:2016+A1:2018 and EN ISO 374-5:2016, plus EN ISO 21420:2020 [not UK designated].

SATRA Technology Centre (Approved Body 0321) performed the UKCA type-examination (Module B) and issued the UKCA type-examination certificate AB0321/16367-01/E00-00 for category 3 PPE, EN374 Type B

is subject to the conformity assessment procedure set out in Module C2 of PPE Regulation 2016/425 under the supervision of SATRA Technology Centre, Wyndham Way, Telford Way, Kettering, NN16 8SD, UK (Approved Body 0321)

UK CA 0321

and

Medical Devices Directive 93/42/EEC (in UK law the Medical Devices Regulations 2002 (SI 2002 No 618, as amended)), Medical Devices Regulation (EU) 2017/745 as amended, and with standards EN455-1:2020, EN455-2:2015, EN455-3:2015 and EN455-4:2009 and are Class I self-certified

UK CA

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

Done at Troisdorf on 26 April 2024.

Sebastian Schuster
Managing Director
UNIGLOVES® Arzt-und Klinikbedarf Handelsgesellschaft mbH

UNIGLOVES®
KEEPING YOU SAFE

Annex I

Product Code	Product description
GA004*	PRO.TECT Black Nitrile
GA005*	PRO.TECT Orange Diamond HD Nitrile
GA006*	PRO.TECT Black HD Nitrile
GA007*	PRO.TECT Black HD+ Nitrile
GA008*	PRO.TECT Green HD Nitrile
GA009*	PRO.TECT Green HD+ Nitrile
GA010*	PRO.TECT Blue XHD+ Nitrile
GA012	PRO.TECT Blue +
GA013*	PRO.TECT Black Diamond HD Nitrile
GA014*	PRO.TECT Max 9N
GM006*	Stronghold Nitrile
GM007*	Stronghold + Nitrile
GU004*	PRO.TECT Blue Nitrile