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, EN ISO 374-5:2016, EN ISO 21420:2020 and EN 420:2003+A1:2009.

CCQS Certification Services Limited (Notified Body 2834) performed the EU type-examination (Module B) and issued the EU type-examination certificate CE-PI-20230418-01-01-9B for category 3 PPE

is subject to the conformity assessment procedure set out in Module C2 of Regulation EU (2016/425) under the supervision of CCQS Certification Services Limited, Block 1, Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Ireland (Notified Body 2834)

CE 2834

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 27 April 2023.

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 standards EN ISO 374-1:2016, EN ISO 374-5:2016 and EN 420:2003+A1:2009.

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

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)

UKCA 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

UKCA

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

Done at Troisdorf on 27 April 2023.

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

UNIGLOVES®
KEEPING YOU SAFE

Annex I

Product Code	Product description
GD003*	Vitality Nitrile
GF001*	Fortified Nitrile
GM004*	Kooltouch Nitrile
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
GP011*	Yellow Pearl Nitrile
GP012*	Burgundy Pearl Nitrile
GP013*	Orange Pearl Nitrile
GS003*	Unicare Nitrile (100s)
GS004*	Unicare Nitrile (200s)
GT003*	Select Black Nitrile