UNIGLOVES®
KEEPING YOU SAFE

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, 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 EN420:2003+A1:2009 / EN ISO 21420:2020.

CE

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 11 January 2022.

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

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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 EN420:2003+A1:2009 / EN ISO 21420:2020.

UK CA

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

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Done at Troisdorf on 11 January 2022.

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

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Annex I

Product Code	Product description
GS005*	Unicare Unitrile
GS006*-A	Unicare Clear Vinyl
GS008*-A	Unicare Blue Vinyl
GS013*-A	Unicare Stretch Vinyl
GU007*-A	Unicare Premium Stretch Vinyl

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