

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 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 and EN ISO 21420:2020.

CCQS Certification Services Limited (Notified Body 2834) performed the EU type-examination (Module B) and issued the EU type-examination certificate CE-PI-20240213-02-01-9A 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 5 March 2024.



Sebastian Schuster
Managing Director

UNIGLOVES® Arzt-und Klinikbedarf Handelsgesellschaft mbH

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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 AB0321/16366-01/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)



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



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Done at Troisdorf on 5 March 2024.



Sebastian Schuster
Managing Director

UNIGLOVES® Arzt-und Klinikbedarf Handelsgesellschaft mbH

Annex I

Product Code	Product description
GS001*	Unicare Latex