

EU Declaration of Conformity

UK Responsible Person

The manufacturer established in the Union:

Unigloves (UK) Limited 3 Ambley Green Gillingham Kent ME8 ONJ UK

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)

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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 25 August 2024.

Sebastian Schuster

Managing Director

UNIGLOVES Arzt-und Klinikbedarf Handelsgesellschaft mbH

UNIGLOVES UK

3 Ambley Green, Gillingham Business Park, Gillingham, Kent, ME8 ONJ

+44 (0)800 049 6602

enquiries@unigloves.co.uk unigloves.co.uk

Registered office: 37 St Margaret's Street, Canterbury, Kent, CT1 2TU Registered in England No. 04010200 VAT registration 791817787

UNIGLOVES GERMANY

Arzt- & Klinikbedarf Handelsgesellschaft mbH

Camp-Spich-Straße 71, D-53842 Troisdorf-Spich

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unigloves@unigloves.de unigloves.de

Geschäftsführer: Sebastian Schuster, Robert Feldmeier Handelsregister Siegburg HRB 5002 USt.-ID Nr. DE 122266038 Steuer-Nr. 220/5864/0164



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3 Ambley Green Camp-Spich-Str. 71 Gillingham 53842 Troisdorf Kent ME8 0NJ Germany

UK

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)



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 selfcertified



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

Done at Troisdorf on 25 August 2024.

Sebastian Schuster **Managing Director**

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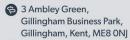
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Annex I

Product Code	Product description
GM010*	CrossGuard

UNIGLOVES UK



2 +44 (0)800 049 6602

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