

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 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 420:2003+A1:2009.

SATRA Technology Europe (Notified Body 2777) performed the EU type-examination (Module B) and issued the EU type-examination certificate 2777/11077-01/E00-00 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 SATRA Technology Europe, Bracetown Business Park, Clonee, D15 YN2P, Ireland (Notified Body 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



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

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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Kent ME8 ONJ UK Germany

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

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

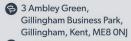


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Annex I

Product Code	Product description
GA001*	PRO.TECT Latex HD

UNIGLOVES UK



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