

## 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.



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**

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 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  
 +49 (0)2241-9323-0  
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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

## UK Declaration of Conformity

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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.



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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## Annex I

Product Code	Product description
GS005*	Unicare Nitrile
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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