

## 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 420:2003+A1:2009.

SATRA Technology Europe (Notified Body 2777) performed the EU type-examination (Module B) and issued the EU type-examination certificate 2777/14052-01/E00-00

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<sup>th</sup> 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  
 +49 (0)2241 9323-297  
 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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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 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 AB0321/16748-01/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)

**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**

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

Done at Troisdorf on 11th January 2022.



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

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## Annex I

Product Code	Product description
GM008*	BioTouch

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