

UD130 JUR-EU-MDR-DOC EC Declaration of Conformity according to Regulation (EU) 2017/745			
QM – Handbuch nach DIN EN ISO 13485:2021		Seite 1 von 3	
Prepared by: Mr. Dreßler	Approval (content/formal): Mr. Dreßler / Ms. Heuser	Release date: 10.09.2025	Revision: 2
Product Family Examination Gloves			
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Medical Device	Unigloves BioTouch Nitrile Gloves
Catalogue number	See Annex
Basic UDI-DI according to Part C of Annex VI	4260503143710R3
Intended Purpose	The non-sterile disposable examination gloves are used to protect patients, users or third parties against diseases and provide temporal protection against bacteria, fungi, viruses and certain chemicals. The examination gloves can be used in the laboratory, medical and industrial sector as well as in the domestic area by laypersons and health care users.
Risk Class according to Annex VIII	I

Manufacturer	Unigloves Arzt- & Klinikbedarf Handelsgesellschaft mbH Camp-Spich-Str. 71 53842 Troisdorf-Spich Germany
Single Registration Number according to Article 31	DE-MF-000013340

We hereby declare, on our own responsibility, the conformity of the abovementioned medical device in accordance with Medical Device Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Unigloves Arzt- & Klinikbedarf Handelsgesellschaft mbH ensures that the medical device that is covered by the present declaration is in conformity with this Regulation and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

Applicable standards and Common Specifications

EN 455-1:2020	
EN455-2:2024	
EN 455-3:2023	
EN 455-4:2009	
Common Specification	None
Conformity assessment	Technical file according to annex II + III of the regulation (EU) 2017/745

Furthermore, we hereby declare that the products as personal protective equipment (PPE) of the category III comply with the provisions of Regulation (EU) 2016/425 of the European Parliament and of the Council of 09

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March 2016 and are identical to the PPE that was the subject of the issued EC type examination with the following certificate numbers:

- 2777/25664-01/E02-01

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

The PPE is subject to the conformity assessment procedure module C2 under the supervision of the Notified Body 2777.

Applied harmonised standards, national standards or other normative documents	EN ISO 21420:2020 + A1:2024, EN ISO 374-1:2016 + A1:2018 / Type B – Test chemicals Sodium Hydroxide 40%, Hydrogen peroxide 30%, Formaldehyde 37%, EN ISO 374-4:2019, EN ISO 374-5:2016
Notified Body	SATRA Technology Europe (Identification number 2777) Bracetown Business Park, Clonee, D15 YN2P, Ireland
Certificates issued	2777/25664-01/E02-01 valid until 30.04.2029
EU Declaration is valid until	02.06.2028

Troisdorf, 29.09.2025



Dr. Sandra Heuser

Person responsible

for regulatory compliance

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Article number	Product description	6 / XS	7 / S	8 / M	9 / L	10 / XL
GM009*	Unigloves BioTouch Black	GM0091	GM0092	GM0093	GM0094	GM0095
GM008*	Unigloves BioTouch	GM0081	GM0082	GM0083	GM0084	GM0085