

UD130 JUR-EU-MDR-DOC EC Declaration of Conformity according to Regulation (EU) 2017/745		 UNIGLOVES®	
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			
Dokumentenrevision:			4

Medical Device	Unigloves Nitrile Gloves PPE Type B
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:

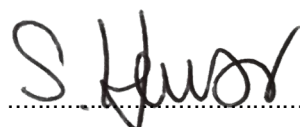
- 2777/22896-01/E00-00

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 n-Heptane, Hydrogen peroxide 30%, Formaldehyde 37%, EN ISO 374-4:2019, EN ISO 374-5:2016
Notified Body	SATRA Technology Europe (Kennnummer 2777) Bracetown Business Park, Clonee, D15 YN2P, Ireland
Certificates issued	2777/22896-01/E00-00 valid until 22.11.2027
EU Declaration is valid until	22.11.2027

Troisdorf, 16.03.2026



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	11 / XXL
111*	Unigloves FORMAT® BLUE 300	NA	1112	1113	1114	1115	1116
GA004*	Unigloves PRO.TECT BLACK	NA	GA0042	GA0043	GA0044	GA0045	NA
GA005*	Unigloves PRO.TECT ORANGE HD	NA	GA0052	GA0053	GA0054	GA0055	NA
GA006*	Unigloves PRO.TECT BLACK HD	GA0061	GA0062	GA0063	GA0064	GA0065	NA
GA007*	PRO.TECT Black HD+	GA0071	GA0072	GA0073	GA0074	GA0075	NA
GA008*	Unigloves PRO.TECT GREEN HD	GA0081	GA0082	GA0083	GA0084	GA0085	NA
GA009*	Unigloves PRO.TECT GREEN HD+	GA0091	GA0092	GA0093	GA0094	GA0095	NA
GA010*	Unigloves PRO.TECT BLUE XHD+	NA	GA0102	GA0103	GA0104	GA0105	NA
GA012*	PRO.TECT Blue +	NA	GA0122	GA0123	GA0124	GA0125	NA
GA013*	Unigloves PRO.TECT Black Diamond HD	NA	NA	GA0133	GA0134	GA0315	NA
GA014*	Unigloves PRO.TECTMAX 9N	NA	GA0142	GA0143	GA0144	GA0145	NA
GM006*	Unigloves STRONGHOLD	GM0061	GM0062	GM0063	GM0064	GM0065	NA
GM007*	Unigloves STRONGHOLD+®	GM0071	GM0072	GM0073	GM0074	GM0075	NA