

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: 03.06.2025	Revision: 2
Product Family Examination Gloves			
Dokumentenrevision:			2

Medical Device	Unigloves Premium Latex Gloves
Catalogue number	See annex
Basic UDI-DI according to Part C of Annex VI	426050314370R3
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:

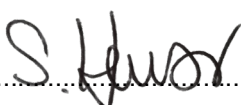
- CE-PI-20240213-03-01-9A

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 2834.

Applied harmonised standards, national standards or other normative documents	EN ISO 21420:2020, 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	CCQS Certification Services Limited (Kennnummer 2834) Block 1 Blanchardstown Corporate Park, Ballycoolin Road, D15 AKK1 Ireland
Certificates issued	CE-PI-20240213-03-01-9A valid until 04.03.2029
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
60*	Unigloves COMFORT® 300	NA	602	603	604	NA
120*	Unigloves COMFORT®	1201	1202	1203	1204	1205
150*	Unigloves CONTACT®	1501	1502	1503	1504	1505
170*	Unigloves DERMA SKIN®	1701	1702	1703	1704	NA
190*	Unigloves LANO-E-GEL®	1901	1902	1903	1904	1905
210*	Unigloves SELECT® BLUE	NA	2102	2103	2104	2105
230*	Unigloves SELECT® PLUS	2301	2302	2303	2304	2305
240*	Unigloves SELECT® BLACK	2401	2402	2403	2404	2405
2430*	Unigloves SELECT® BLACK 300	24301	24302	24303	24304	24305