

UD130 JUR-EU-MDR-DOC EC Declaration of Conformity according to Regulation (EU) 2017/745		 UNIGLOVES®	
QM manual according to DIN EN ISO 13485:2021		Page 1 von 6	
Prepared by: Mr. Dreßler	Approval (content/formal): Mr. Dreßler / Ms. Heuser	Release date: 10.09.2025	Revision: 2
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Medical Device	Unigloves Nitrile Gloves PPE Type C
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:

- CE-PI-20230418-01-01-9B

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 + A1:2016/ Type C – Test chemical Sodium hydroxide 40%, 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-20230418-01-01-9B valid until 26.04.2028
EU Declaration is valid until	26.04.2028

Troisdorf, 29.09.2025



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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
100*	Unigloves FORMAT® WHITE	1001	1002	1003	1004	1005	NA
101*	Unigloves COBALT PEARL®	1011	1012	1013	1014	1015	NA
350*	Unigloves LIME PEARL®	3501	3502	3503	3504	NA	NA
380*	Unigloves BLACK PEARL®	3801	3802	3803	3804	NA	NA
410*	Unigloves OPAL PEARL®	4101	4102	4103	4104	4105	NA
450*	Unigloves YELLOW PEARL®	4501	4502	4503	4504	4505	NA
460*	Unigloves ORANGE PEARL®	4601	4602	4603	4604	4605	NA
480*	Unigloves VIOLET PEARL®	4801	4802	4803	4804	NA	NA
580*	Unigloves PINK PEARL®	5801	NA	NA	5804	NA	NA
600*	Unigloves FORMAT® BLUE	NA	6002	6003	6004	6005	NA
651*	Unigloves SAPPHIRE PEARL®	6511	NA	6513	NA	NA	NA
680*	Unigloves MINT PEARL®	6801	6802	6803	NA	6805	NA
750*	Unigloves FANCY® ROSE	7501	7502	7503	7504	NA	NA
751*	Unigloves FANCY® GOLD	7511	7512	7513	7514	7515	NA

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752*	Unigloves FANCY® SILVER	7521	7522	7523	7524	7525	NA
753*	Unigloves FANCY® VIOLET	7531	7532	7533	7534	NA	NA
80*0	Unigloves SOFT® NITRIL BLUE	NA	8020	8030	8040	8050	NA
850*	Unigloves MAGENTA PEARL®	8501	NA	NA	NA	8505	NA
880*	Unigloves BLUE PEARL®	NA	NA	NA	NA	8805	NA
980*	Unigloves RED PEARL®	9801	9802	9803	NA	9805	NA
1410*	Unigloves SOFT® NITRIL BLUE 300	NA	14102	14103	14104	14105	NA
700*-200	Unigloves SOFT® WHITE	NA	7002- 200	7003- 200	7004- 200	7005- 200	NA
70*0 W	Unigloves SOFT® NITRIL WHITE PREMIUM	7010 W	NA	NA	NA	NA	NA
800*-200	Unigloves SOFT® BLUE	NA	8002- 200	8003- 200	8004- 200	8005- 200	NA
80*0-374	Unigloves SOFT® NITRIL BLUE PREMIUM	8010- 374	8020- 374	8030- 374	8040- 374	8050- 374	NA
900*-200	Unigloves SOFT® BLACK	NA	9002- 200	9003- 200	9004- 200	9005- 200	NA
GM010*	Unigloves CROSSGUARD	GM0101	GM0102	GM0103	GM0104	GM0105	NA

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GP001*	Unigloves BLUE PEARL®	GP0011	GP0012	GP0013	GP0014	GP0015	NA
GP002+	Unigloves WHITE PEARL®	GP0021	GP0022	GP0023	GP0024	GP0025	NA
GP003*	Unigloves BLACK PEARL®	GP0031	GP0032	GP0033	GP0034	GP0035	NA
GP004*	Unigloves GREEN PEARL®	GP0041	GP0042	GP0043	GP0044	GP0045	NA
GP005*	Unigloves PINK PEARL®	GP0051	GP0052	GP0053	GP0054	GP0055	NA
GP006*	Unigloves RED PEARL®	NA	GP0062	GP0063	GP0064	GP0065	NA
GP007*	Unigloves VIOLET PEARL®	GP0071	GP0072	GP0073	GP0074	GP0075	NA
GP008*	Unigloves SAPPHIRE PEARL®	GP0081	GP0082	GP0083	GP0084	GP0085	NA
GP009*	Unigloves OPAL PEARL®	GP0091	GP0092	GP0093	GP0094	GP0095	NA
GP012*	Unigloves BURGUNDY PEARL®	GP0121	GP0122	GP0123	GP0124	GP0125	NA
GP101*	Unigloves COBALT PEARL®	GP1011	GP1012	GP1013	GP1014	GP1015	NA
GP350*	Unigloves LIME PEARL®	GP3501	GP3502	GP3503	GP3504	GP3505	NA
GP680*	Unigloves MINT PEARL®	GP6801	GP6802	GP6803	GP6804	GP6805	NA
GP850*	Unigloves MAGENTA PEARL®	GP8501	GP8502	GP8503	GP8504	GP8505	NA
GS004*	Unigloves UNICARE Blue Nitrile	NA	GS0042	GS0043	GS0044	GS0045	NA
GS025*	Unigloves UNICARE Black Nitrile	GS0251	GS0252	GS0253	GS0254	GS0255	NA

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GS003*	Unigloves UNICARE Nitrile	GS0031	GS0032	GS0033	GS0034	GS0035	NA
GS700*	Unigloves UNICARE White Nitrile	NA	GS0072	GS0073	GS0074	GS0075	NA
GS900*	Unigloves UNICARE Black Nitrile	NA	GS9002	GS9003	GS9004	GS9005	NA