



UNIGLOVES®

EU Declaration of Conformity
**according to Regulation (EU) 2017/745 of the European
Parliament and of the Council of 5 April 2017 on Medical
Devices**

Medical Device	UNIGLOVES Examination Gloves
Article number	See appendix
Basic UDI-DI according to Annex VI Part C	4260503143710R3
Intended Use	The non-sterile disposable examination gloves are used to protect patients, users or third parties against diseases and provide temporal protection against bacteria, fungi 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, Rule 1 and 5	I

Manufacturer	UNIGLOVES Arzt- & Klinikbedarf Handelsgesellschaft mbH Camp-Spich-Str. 71 53842 Troisdorf-Spich Germany
Single Registration Number gemäß Artikel 31	Not available yet

We hereby declare on our own responsibility the conformity of the above-mentioned medical devices in accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council of 05 April 2017 concerning medical devices.

UNIGLOVES Arzt- & Klinikbedarf Handelsgesellschaft mbH hereby declares that medical devices covered by this declaration comply with this Regulation and, where applicable, other relevant Union legislation providing for the drawing up of an EU declaration of conformity.

Conformity for the above medical devices is in accordance with the applicable specifications:

EN 455-1:2000	
EN 455-2:2015	
EN 455-3:2015	
EN 455-4:2009	
Common specification	None

Chosen conformity assessment procedure	Technical File according to annex II und annex III
Validity of this CE declaration of conformity	Valid until 02.06.2022



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according to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices

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

- 2777/10887-05/E01-01 for the variant Nitrile
- 2777/12332-01/E06-02 for the variant Latex

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 420:2003 + A1:2009, EN ISO 374-1:2016 / Type C – Tested chemical 40% Sodium hydroxide, EN ISO 374-4:2013, EN ISO 374-5:2016
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Conformity assessment body	Notified Body 2777 SATRA Technology Europe Bracetown Business Park Clonee D15 YN2P Ireland
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Troisdorf, 03.05.2021

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CEO, Sebastian Schuster

Appendix to the Declaration of Conformity

Article number	Description
602	Unigloves COMFORT 300 Latexhandschuhe
603	Unigloves COMFORT 300 Latexhandschuhe
604	Unigloves COMFORT 300 Latexhandschuhe
1001	Unigloves FORMAT WHITE - EN 374
1002	Unigloves FORMAT WHITE - EN 374
1003	Unigloves FORMAT WHITE - EN 374
1004	Unigloves FORMAT WHITE - EN 374
1005	Unigloves FORMAT WHITE - EN 374
1011	Unigloves COBALT PEARL Nitrilhandschuhe
1012	Unigloves COBALT PEARL Nitrilhandschuhe
1013	Unigloves COBALT PEARL Nitrilhandschuhe
1014	Unigloves COBALT PEARL Nitrilhandschuhe
1015	Unigloves COBALT PEARL Nitrilhandschuhe
1112	Unigloves Format BLUE 300 Nitrilhandschuhe
1113	Unigloves Format BLUE 300 Nitrilhandschuhe
1114	Unigloves Format BLUE 300 Nitrilhandschuhe
1115	Unigloves Format BLUE 300 Nitrilhandschuhe
1116	Unigloves Format BLUE 300 Nitrilhandschuhe
1201	Unigloves COMFORT Latexhandschuhe
1202	Unigloves COMFORT Latexhandschuhe
1203	Unigloves COMFORT Latexhandschuhe
1204	Unigloves COMFORT Latexhandschuhe
1205	Unigloves COMFORT Latexhandschuhe
1501	Unigloves CONTACT Latexhandschuhe
1502	Unigloves CONTACT Latexhandschuhe
1503	Unigloves CONTACT Latexhandschuhe
1504	Unigloves CONTACT Latexhandschuhe
1505	Unigloves CONTACT Latexhandschuhe
1701	Unigloves DERMA SKIN Latexhandschuhe
1702	Unigloves DERMA SKIN Latexhandschuhe
1703	Unigloves DERMA SKIN Latexhandschuhe
1704	Unigloves DERMA SKIN Latexhandschuhe
1901	Unigloves LANO-E-GEL Latexhandschuhe
1902	Unigloves LANO-E-GEL Latexhandschuhe
1903	Unigloves LANO-E-GEL Latexhandschuhe
1904	Unigloves LANO-E-GEL Latexhandschuhe
1905	Unigloves LANO-E-GEL Latexhandschuhe
2102	Unigloves SELECT BLUE Latexhandschuhe
2103	Unigloves SELECT BLUE Latexhandschuhe
2104	Unigloves SELECT BLUE Latexhandschuhe
2105	Unigloves SELECT BLUE Latexhandschuhe
2301	Unigloves SELECT PLUS Latexhandschuhe
2302	Unigloves SELECT PLUS Latexhandschuhe
2303	Unigloves SELECT PLUS Latexhandschuhe
2304	Unigloves SELECT PLUS Latexhandschuhe
2305	Unigloves SELECT PLUS Latexhandschuhe
2401	Unigloves SELECT BLACK Latexhandschuhe

2402 Unigloves SELECT BLACK Latexhandschuhe
2403 Unigloves SELECT BLACK Latexhandschuhe
2404 Unigloves SELECT BLACK Latexhandschuhe
2405 Unigloves SELECT BLACK Latexhandschuhe
2801 Unigloves WHITE PEARL Nitrilhandschuhe
2802 Unigloves WHITE PEARL Nitrilhandschuhe
2803 Unigloves WHITE PEARL Nitrilhandschuhe
2804 Unigloves WHITE PEARL Nitrilhandschuhe
2805 Unigloves WHITE PEARL Nitrilhandschuhe
2902 Unigloves BLACK LATEX Latexhandschuhe
2903 Unigloves BLACK LATEX Latexhandschuhe
2904 Unigloves BLACK LATEX Latexhandschuhe
2905 Unigloves BLACK LATEX Latexhandschuhe
3201 Unigloves Natural Latex Glove
3202 Unigloves Natural Latex Glove
3203 Unigloves Natural Latex Glove
3204 Unigloves Natural Latex Glove
3205 Unigloves Natural Latex Glove
3402 Unigloves Blue Nitrile Gloves
3403 Unigloves Blue Nitrile Gloves
3404 Unigloves Blue Nitrile Gloves
3405 Unigloves Blue Nitrile Gloves
3501 Unigloves GREEN PEARL Nitrilhandschuhe
3502 Unigloves GREEN PEARL Nitrilhandschuhe
3503 Unigloves GREEN PEARL Nitrilhandschuhe
3504 Unigloves GREEN PEARL Nitrilhandschuhe
3505 Unigloves GREEN PEARL Nitrilhandschuhe
3801 Unigloves BLACK PEARL Nitrilhandschuhe
3802 Unigloves BLACK PEARL Nitrilhandschuhe
3803 Unigloves BLACK PEARL Nitrilhandschuhe
3804 Unigloves BLACK PEARL Nitrilhandschuhe
3805 Unigloves BLACK PEARL Nitrilhandschuhe
4101 Unigloves OPAL PEARL Nitrilhandschuhe
4102 Unigloves OPAL PEARL Nitrilhandschuhe
4103 Unigloves OPAL PEARL Nitrilhandschuhe
4104 Unigloves OPAL PEARL Nitrilhandschuhe
4105 Unigloves OPAL PEARL Nitrilhandschuhe
4501 Unigloves YELLOW PEARL Nitrilhandschuhe
4502 Unigloves YELLOW PEARL Nitrilhandschuhe
4503 Unigloves YELLOW PEARL Nitrilhandschuhe
4504 Unigloves YELLOW PEARL Nitrilhandschuhe
4505 Unigloves YELLOW PEARL Nitrilhandschuhe
4801 Unigloves VIOLET PEARL Nitrilhandschuhe
4802 Unigloves VIOLET PEARL Nitrilhandschuhe
4803 Unigloves VIOLET PEARL Nitrilhandschuhe
4804 Unigloves VIOLET PEARL Nitrilhandschuhe
4805 Unigloves VIOLET PEARL Nitrilhandschuhe
5801 Unigloves PINK PEARL Nitrilhandschuhe
5802 Unigloves PINK PEARL Nitrilhandschuhe
5803 Unigloves PINK PEARL Nitrilhandschuhe

5804	Unigloves PINK PEARL Nitrilhandschuhe
6002	Unigloves FORMAT BLUE - EN 374
6003	Unigloves FORMAT BLUE - EN 374
6004	Unigloves FORMAT BLUE - EN 374
6005	Unigloves FORMAT BLUE - EN 374
6511	Unigloves SAPHIR PEARL Nitrilhandschuhe
6512	Unigloves SAPHIR PEARL Nitrilhandschuhe
6513	Unigloves SAPHIR PEARL Nitrilhandschuhe
6514	Unigloves SAPHIR PEARL Nitrilhandschuhe
6515	Unigloves SAPHIR PEARL Nitrilhandschuhe
6801	Unigloves Mint PEARL Nitrilhandschuhe
6802	Unigloves Mint PEARL Nitrilhandschuhe
6803	Unigloves Mint PEARL Nitrilhandschuhe
6804	Unigloves Mint PEARL Nitrilhandschuhe
6805	Unigloves Mint PEARL Nitrilhandschuhe
7801	Unigloves PEACH PEARL Nitrilhandschuhe
7802	Unigloves PEACH PEARL Nitrilhandschuhe
7803	Unigloves PEACH PEARL Nitrilhandschuhe
7804	Unigloves PEACH PEARL Nitrilhandschuhe
8501	Unigloves MAGENTA PEARL Nitrilhandschuhe
8502	Unigloves MAGENTA PEARL Nitrilhandschuhe
8503	Unigloves MAGENTA PEARL Nitrilhandschuhe
8504	Unigloves MAGENTA PEARL Nitrilhandschuhe
8505	Unigloves MAGENTA PEARL Nitrilhandschuhe
8801	Unigloves BLUE PEARL Nitrilhandschuh
8802	Unigloves BLUE PEARL Nitrilhandschuh
8803	Unigloves BLUE PEARL Nitrilhandschuh
8804	Unigloves BLUE PEARL Nitrilhandschuh
8805	Unigloves BLUE PEARL Nitrilhandschuh
9002	UNIGLOVES Soft Nitril Black 100
9003	UNIGLOVES Soft Nitril Black 100
9004	UNIGLOVES Soft Nitril Black 100
9005	UNIGLOVES Soft Nitril Black 100
9801	Unigloves RED PEARL Nitrilhandschuhe
9802	Unigloves RED PEARL Nitrilhandschuhe
9803	Unigloves RED PEARL Nitrilhandschuhe
9804	Unigloves RED PEARL Nitrilhandschuhe
9805	Unigloves RED PEARL Nitrilhandschuhe
14102	Unigloves SOFT NITRIL BLUE 300 Nitrilhandschuhe
14103	Unigloves SOFT NITRIL BLUE 300 Nitrilhandschuhe
14104	Unigloves SOFT NITRIL BLUE 300 Nitrilhandschuhe
14105	Unigloves SOFT NITRIL BLUE 300 Nitrilhandschuhe
14106	Unigloves SOFT NITRIL BLUE 300 Nitrilhandschuhe
24301	Unigloves SELECT BLACK 300 Latexhandschuhe
24302	Unigloves SELECT BLACK 300 Latexhandschuhe
24303	Unigloves SELECT BLACK 300 Latexhandschuhe
24304	Unigloves SELECT BLACK 300 Latexhandschuhe
24305	Unigloves SELECT BLACK 300 Latexhandschuhe

7002-200	Nitrilhandschuhe SOFT White
7003-200	Nitrilhandschuhe SOFT White
7004-200	Nitrilhandschuhe SOFT White
7005-200	Nitrilhandschuhe SOFT White
7010 W	UNIGLOVES Soft Nitril White Premium
7020 W	UNIGLOVES Soft Nitril White Premium
7030 W	UNIGLOVES Soft Nitril White Premium
7040 W	UNIGLOVES Soft Nitril White Premium
7050 W	UNIGLOVES Soft Nitril White Premium
8002-200	Nitrilhandschuhe SOFT BLUE
8003-200	Nitrilhandschuhe SOFT BLUE
8004-200	Nitrilhandschuhe SOFT BLUE
8005-200	Nitrilhandschuhe SOFT BLUE
8006-200	Nitrilhandschuhe SOFT BLUE
8010-374	UNIGLOVES Soft Nitril Blue Premium
8020-374	UNIGLOVES Soft Nitril Blue Premium
8030-374	UNIGLOVES Soft Nitril Blue Premium
8040-374	UNIGLOVES Soft Nitril Blue Premium
8050-374	UNIGLOVES Soft Nitril Blue Premium
9002-200	UNIGLOVES Soft Nitril Black
9003-200	UNIGLOVES Soft Nitril Black
9004-200	UNIGLOVES Soft Nitril Black
9005-200	UNIGLOVES Soft Nitril Black
GM0061	UNIGLOVES Stronghold Nitrilhandschuh
GM0062	UNIGLOVES Stronghold Nitrilhandschuh
GM0063	UNIGLOVES Stronghold Nitrilhandschuh
GM0064	UNIGLOVES Stronghold Nitrilhandschuh
GM0065	UNIGLOVES Stronghold Nitrilhandschuh
GM0071	UNIGLOVES Stronghold PLUS Nitrilhandschuh
GM0072	UNIGLOVES Stronghold PLUS Nitrilhandschuh
GM0073	UNIGLOVES Stronghold PLUS Nitrilhandschuh
GM0074	UNIGLOVES Stronghold PLUS Nitrilhandschuh
GM0075	UNIGLOVES Stronghold PLUS Nitrilhandschuh
GP0021	Unigloves UK WHITE PEARL Nitrilhandschuhe
GP0022	Unigloves UK WHITE PEARL Nitrilhandschuhe
GP0023	Unigloves UK WHITE PEARL Nitrilhandschuhe
GP0024	Unigloves UK WHITE PEARL Nitrilhandschuhe
GP0025	Unigloves UK WHITE PEARL Nitrilhandschuhe
GP0041	Unigloves UK GREEN PEARL Nitrilhandschuhe
GP0042	Unigloves UK GREEN PEARL Nitrilhandschuhe
GP0043	Unigloves UK GREEN PEARL Nitrilhandschuhe
GP0044	Unigloves UK GREEN PEARL Nitrilhandschuhe
GP0045	Unigloves UK GREEN PEARL Nitrilhandschuhe
GP0061	Unigloves UK RED PEARL Nitrilhandschuhe
GP0062	Unigloves UK RED PEARL Nitrilhandschuhe
GP0063	Unigloves UK RED PEARL Nitrilhandschuhe
GP0064	Unigloves UK RED PEARL Nitrilhandschuhe
GP0065	Unigloves UK RED PEARL Nitrilhandschuhe

GP0073	Unigloves UK VIOLET PEARL Nitrilhandschuhe
GP0074	Unigloves UK VIOLET PEARL Nitrilhandschuhe
GP0075	Unigloves UK VIOLET PEARL Nitrilhandschuhe
GS0031	UNICARE Soft Nitril Nitrilhandschuh
GS0032	UNICARE Soft Nitril Nitrilhandschuh
GS0033	UNICARE Soft Nitril Nitrilhandschuh
GS0034	UNICARE Soft Nitril Nitrilhandschuh
GS0035	UNICARE Soft Nitril Nitrilhandschuh