


QMH4_23TD90		 UNIGLOVES®	
JUR-EU-MDR-DOC EC Declaration of Conformity according to Regulation (EU) 2017/745			
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Erstellt: Hr. Dreßler	Freigabe (inhaltlich/formal): Hr. Dreßler / Fr. Heuser	Freigabedatum: 22.01.2024	Revision: 3
Product Family Examination Gloves			

Medical Device	Unigloves Nitrile Examination Gloves
Catalogue number	See annex to the declaration of conformity
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	
EN 455-2:2015	
EN 455-3:2015	
EN 455-4:2009	
Common Specification	None
Conformity assessment	Technical file according to annex II + III of the regulation (EU) 2017/745

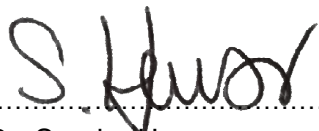
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Furthermore, we hereby declare that the products as personal protective equipment (PPE) of the category III comply with the provisions of Regulation (EU) 2016/425 of the European Parliament and of the Council of 09 March 2016 and are identical to the PPE that was the subject of the issued EC type examination with the certificate number CE-PI-20230418-01-01-9A.


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 C – Tested chemical 40% Sodium hydroxide, EN ISO 374-4:2019, EN ISO 374-5:2016
Notified Body	Notified Body 2834 CCQS Certification Services Limited, Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin15 D15 AKK1 Ireland
Certificates issued	CE certificate CE-PI-20230418-01-01-9A valid until 27.04.2028
EU Declaration is valid until	02.06.2025

Troisdorf, 25.03.2024




Dr. Sandra Heuser
*Person responsible
for regulatory compliance*


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Annex to the Declaration of Conformity


Article No.	Description	Size
1001	Unigloves FORMAT® WHITE	XS
1002	Unigloves FORMAT® WHITE	S
1003	Unigloves FORMAT® WHITE	M
1004	Unigloves FORMAT® WHITE	L
1005	Unigloves FORMAT® WHITE	XL
1011	Unigloves COBALT PEARL®	XS
1012	Unigloves COBALT PEARL®	S
1013	Unigloves COBALT PEARL®	M
1014	Unigloves COBALT PEARL®	L
1015	Unigloves COBALT PEARL®	XL
14102	Unigloves SOFT® NITRIL BLUE 300	S
14103	Unigloves SOFT® NITRIL BLUE 300	M
14104	Unigloves SOFT® NITRIL BLUE 300	L
14105	Unigloves SOFT® NITRIL BLUE 300	XL
14106	Unigloves SOFT® NITRIL BLUE 300	XXL
2801	Unigloves WHITE PEARL®	XS
2802	Unigloves WHITE PEARL®	S
2803	Unigloves WHITE PEARL®	M
2804	Unigloves WHITE PEARL®	L
2805	Unigloves WHITE PEARL®	XL
3501	Unigloves LIME PEARL®	XS
3502	Unigloves LIME PEARL®	S
3503	Unigloves LIME PEARL®	M
3504	Unigloves LIME PEARL®	L
3505	Unigloves LIME PEARL®	XL
3801	Unigloves BLACK PEARL®	XS
3802	Unigloves BLACK PEARL®	S
3803	Unigloves BLACK PEARL®	M
3804	Unigloves BLACK PEARL®	L
3805	Unigloves BLACK PEARL®	XL
4101	Unigloves OPAL PEARL®	XS
4102	Unigloves OPAL PEARL®	S
4103	Unigloves OPAL PEARL®	M
4104	Unigloves OPAL PEARL®	L

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Article No.	Description	Size
4105	Unigloves OPAL PEARL®	XL
4501	Unigloves YELLOW PEARL®	XS
4502	Unigloves YELLOW PEARL®	S
4503	Unigloves YELLOW PEARL®	M
4504	Unigloves YELLOW PEARL®	L
4505	Unigloves YELLOW PEARL®	XL
4601	Unigloves ORANGE PEARL®	XS
4602	Unigloves ORANGE PEARL®	S
4603	Unigloves ORANGE PEARL®	M
4604	Unigloves ORANGE PEARL®	L
4605	Unigloves ORANGE PEARL®	XL
4801	Unigloves VIOLET PEARL®	XS
4802	Unigloves VIOLET PEARL®	S
4803	Unigloves VIOLET PEARL®	M
4804	Unigloves VIOLET PEARL®	L
4805	Unigloves VIOLET PEARL®	XL
5801	Unigloves PINK PEARL®	XS
5802	Unigloves PINK PEARL®	S
5803	Unigloves PINK PEARL®	M
5804	Unigloves PINK PEARL®	L
6002	Unigloves FORMAT® BLUE	S
6003	Unigloves FORMAT® BLUE	M
6004	Unigloves FORMAT® BLUE	L
6005	Unigloves FORMAT® BLUE	XL
6511	Unigloves SAPPHIRE PEARL®	XS
6512	Unigloves SAPPHIRE PEARL®	S
6513	Unigloves SAPPHIRE PEARL®	M
6514	Unigloves SAPPHIRE PEARL®	L
6515	Unigloves SAPPHIRE PEARL®	XL
6801	Unigloves MINT PEARL®	XS
6802	Unigloves MINT PEARL®	S
6803	Unigloves MINT PEARL®	M
6804	Unigloves MINT PEARL®	L
6805	Unigloves MINT PEARL®	XL
7002-200	Unigloves SOFT® WHITE	S

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Article No.	Description	Size
7003-200	Unigloves SOFT® WHITE	M
7004-200	Unigloves SOFT® WHITE	L
7005-200	Unigloves SOFT® WHITE	XL
7010 W	Unigloves SOFT® NITRIL WHITE PREMIUM	XS
7020 W	Unigloves SOFT® NITRIL WHITE PREMIUM	S
7030 W	Unigloves SOFT® NITRIL WHITE PREMIUM	M
7040 W	Unigloves SOFT® NITRIL WHITE PREMIUM	L
7050 W	Unigloves SOFT® NITRIL WHITE PREMIUM	XL
7501	Unigloves FANCY® ROSE	XS
7502	Unigloves FANCY® ROSE	S
7503	Unigloves FANCY® ROSE	M
7504	Unigloves FANCY® ROSE	L
7511	Unigloves FANCY® GOLD	XS
7512	Unigloves FANCY® GOLD	S
7513	Unigloves FANCY® GOLD	M
7514	Unigloves FANCY® GOLD	L
7515	Unigloves FANCY® GOLD	XL
7521	Unigloves FANCY® SILVER	XS
7522	Unigloves FANCY® SILVER	S
7523	Unigloves FANCY® SILVER	M
7524	Unigloves FANCY® SILVER	L
7525	Unigloves FANCY® SILVER	XL
7531	Unigloves FANCY® VIOLET	XS
7532	Unigloves FANCY® VIOLET	S
7533	Unigloves FANCY® VIOLET	M
7534	Unigloves FANCY® VIOLET	L
8002-200	Unigloves SOFT® BLUE	S
8003-200	Unigloves SOFT® BLUE	M
8004-200	Unigloves SOFT® BLUE	L
8005-200	Unigloves SOFT® BLUE	XL
8006-200	Unigloves SOFT® BLUE	XXL
8020	Unigloves SOFT® NITRIL BLUE	S
8030	Unigloves SOFT® NITRIL BLUE	M
8040	Unigloves SOFT® NITRIL BLUE	L
8050	Unigloves SOFT® NITRIL BLUE	XL

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Article No.	Description	Size
8010-374	Unigloves SOFT® NITRIL BLUE PREMIUM	XS
8020-374	Unigloves SOFT® NITRIL BLUE PREMIUM	S
8030-374	Unigloves SOFT® NITRIL BLUE PREMIUM	M
8040-374	Unigloves SOFT® NITRIL BLUE PREMIUM	L
8050-374	Unigloves SOFT® NITRIL BLUE PREMIUM	XL
8501	Unigloves MAGENTA PEARL®	XS
8502	Unigloves MAGENTA PEARL®	S
8503	Unigloves MAGENTA PEARL®	M
8504	Unigloves MAGENTA PEARL®	L
8505	Unigloves MAGENTA PEARL®	XL
8801	Unigloves BLUE PEARL®	XS
8802	Unigloves BLUE PEARL®	S
8803	Unigloves BLUE PEARL®	M
8804	Unigloves BLUE PEARL®	L
8805	Unigloves BLUE PEARL®	XL
9002-200	Unigloves SOFT® BLACK	S
9003-200	Unigloves SOFT® BLACK	M
9004-200	Unigloves SOFT® BLACK	L
9005-200	Unigloves SOFT® BLACK	XL
9801	Unigloves RED PEARL®	XS
9802	Unigloves RED PEARL®	S
9803	Unigloves RED PEARL®	M
9804	Unigloves RED PEARL®	L
9805	Unigloves RED PEARL®	XL
GA0052	Unigloves® PRO.TECT ORANGE HD	S
GA0053	Unigloves® PRO.TECT ORANGE HD	M
GA0054	Unigloves® PRO.TECT ORANGE HD	L
GA0055	Unigloves® PRO.TECT ORANGE HD	XL
GM0092	Unigloves BioTouch Black	S
GM0093	Unigloves BioTouch Black	M
GM0094	Unigloves BioTouch Black	L
GM0095	Unigloves BioTouch Black	XL