


QMH4_23TD90		 UNIGLOVES®	
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 4	
Erstellt: Hr. Dreßler	Freigabe (inhaltlich/formal): Hr. Dreßler / Fr. Heuser	Freigabedatum: 12.07.2023	Revision: 2
Product Family Examination Gloves			

Medical Device	Unigloves Latex Examination Gloves
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	
EN 455-2:2015	
EN 455-3:2015	
EN 455-4:2009	
Conformity assessment	Technical file according to annex II + III of 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 March 2016 and are identical to the PPE that was the subject of the issued EC type examination with the following certificate numbers:

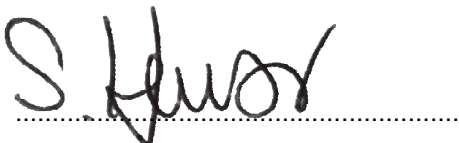
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- CE-PI-20240213-03-01-9A for the premium latex examination gloves
- CE-PI-20240213-02-01-9A for the standard latex examination gloves

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 – Tested chemical Sodium hydroxide 40%, Sodium hydroxide 30%, Formaldehyde 37% 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 Dublin, D15 AKK1 Ireland
Certificates issued	CE-PI-20240213-03-01-9A valid until 04.03.2029 CE-PI-20240213-02-01-9A valid until 04.03.2029
EU Declaration is valid until	02.06.2025


Troisdorf, 14.03.2024



Dr. Sandra Heuser


Person responsible

for regulatory compliance

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Annex to the Declaration of Conformity

Article No.	Description	Size
602	Unigloves COMFORT® 300	S
603	Unigloves COMFORT® 300	M
604	Unigloves COMFORT® 300	L
1201	Unigloves COMFORT®	XS
1202	Unigloves COMFORT®	S
1203	Unigloves COMFORT®	M
1204	Unigloves COMFORT®	L
1205	Unigloves COMFORT®	XL
1301	Unigloves SAFETEC®	XS
1302	Unigloves SAFETEC®	S
1303	Unigloves SAFETEC®	M
1304	Unigloves SAFETEC®	L
1305	Unigloves SAFETEC®	XL
1501	Unigloves CONTACT®	XS
1502	Unigloves CONTACT®	S
1503	Unigloves CONTACT®	M
1504	Unigloves CONTACT®	L
1505	Unigloves CONTACT®	XL
1701	Unigloves DERMA SKIN®	XS
1702	Unigloves DERMA SKIN®	S
1703	Unigloves DERMA SKIN®	M
1704	Unigloves DERMA SKIN®	L
1901	Unigloves LANO-E-GEL®	XS
1902	Unigloves LANO-E-GEL®	S
1903	Unigloves LANO-E-GEL®	M
1904	Unigloves LANO-E-GEL®	L
1905	Unigloves LANO-E-GEL®	XL
2102	Unigloves SELECT® BLUE	S

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2103	Unigloves SELECT® BLUE	M
2104	Unigloves SELECT® BLUE	L
2105	Unigloves SELECT® BLUE	XL
2301	Unigloves SELECT® PLUS	XS
2302	Unigloves SELECT® PLUS	S
2303	Unigloves SELECT® PLUS	M
2304	Unigloves SELECT® PLUS	L
2305	Unigloves SELECT® PLUS	XL
2401	Unigloves SELECT® BLACK	XS
2402	Unigloves SELECT® BLACK	S
2403	Unigloves SELECT® BLACK	M
2404	Unigloves SELECT® BLACK	L
2405	Unigloves SELECT® BLACK	XL
24301	Unigloves SELECT® BLACK 300	XS
24302	Unigloves SELECT® BLACK 300	S
24303	Unigloves SELECT® BLACK 300	M
24304	Unigloves SELECT® BLACK 300	L
24305	Unigloves SELECT® BLACK 300	XL