


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 3	
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 to the declaration of conformity
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.

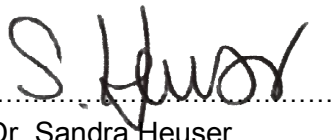
Applicable standards and Common Specifications

EN 455-1:2020	
EN 455-2:2015	
EN 455-3:2015	
EN 455-4:2009	
Common Specification	None
Conformity assessment	Technical file according to annex II + III of the regulation (EU) 2017/745


EU Declaration is valid until	02.06.2025
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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
1101	Unigloves CLASSIC®	XS
1102	Unigloves CLASSIC®	S
1103	Unigloves CLASSIC®	M
1104	Unigloves CLASSIC®	L
1105	Unigloves CLASSIC®	XL
1922	Unigloves PREMIUM®	S
1923	Unigloves PREMIUM®	M
1924	Unigloves PREMIUM®	L
1925	Unigloves PREMIUM®	XL