

UD130 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	
Prepared by: Mr. Dreßler	Approval (content/formal): Mr. Dreßler / Ms. Heuser	Release date: 10.09.2025	Revision: 2
Product Family Examination Gloves			
Document revision:			2

Medical Device	Unigloves Latex and Vinyl 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 intended to protect patients, users or third parties against diseases. The examination gloves can be used in the laboratory and medical sector as well as in the domestic area by laypersons and users in the healthcare sector.
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.

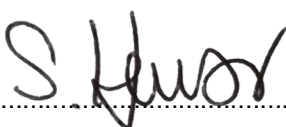
Applicable standards and Common Specifications

DIN EN ISO 13485:2021	Medical devices – Quality management systems – requirements for regulatory purpose
DIN EN ISO 14971:2022	Medical devices – Application of risk management to medical devices
Common Specification:	None
Conformity assessment	Technical file according to annex II + III of the regulation (EU) 2017/745

EU Declaration is valid until	02.06.2028
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Troisdorf, 16.09.2025



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
110*	Unigloves CLASSIC Latex	1101	1102	1103	1104	1105
192*	Unigloves PREMIUM Vinyl	NA	1922	1923	1924	1925