

UD130 JUR-EU-MDR-DOC EC Declaration of Conformity according to Regulation (EU) 2017/745		 UNIGLOVES®	
QM – Handbuch nach DIN EN ISO 13485:2021		Page 1 of 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 UNICARE Classic Latex powdered PPE CAT I
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 protection against low chemical risks. 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	
EN455-2:2024	
EN 455-3:2023	
EN 455-4:2009	
Common Specification	None
Conformity assessment	Technical file according to annex II + III of the regulation (EU) 2017/745

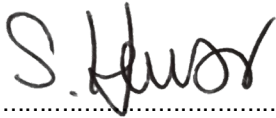
Furthermore, we hereby declare that the products as personal protective equipment (PPE) of the category I comply with the provisions of Regulation (EU) 2016/425 of the European Parliament and of the Council of 09 March 2016.

UD130 JUR-EU-MDR-DOC EC Declaration of Conformity according to Regulation (EU) 2017/745		 UNIGLOVES®	
QM – Handbuch nach DIN EN ISO 13485:2021		Page 2 of 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

This declaration of conformity is issued under the sole responsibility of the manufacturer.

EU Declaration is valid until	02.06.2028
-------------------------------	------------

Troisdorf, 17.03.2026



.....
 Dr. Sandra Heuser
Person responsible
for regulatory compliance

UD130 JUR-EU-MDR-DOC EC Declaration of Conformity according to Regulation (EU) 2017/745			
QM – Handbuch nach DIN EN ISO 13485:2021		Page 3 of 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

Article number	Product description	6 / XS	7 / S	8 / M	9 / L	10 / XL
GS002*	Unigloves UNICARE Classic Latex powdered	GS0021	GS0022	GS0023	GS0024	GS0025