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| **UD130**<br><br>**JUR-EU-MDR-DOC**<br>**EC Declaration of Conformity according to Regulation (EU) 2017/745** | | UNIGLOVES® | |
| QM – Handbuch nach DIN EN ISO 13485:2021 | | Seite 1 von 3 | |
| Prepared by:<br>Mr. Dreßler | Approval (content/formal):<br>Mr. Dreßler / Ms. Heuser | Release date:<br>03.06.2025 | Revision: 2 |
| **Product Family Examination Gloves** | | | |
| Document revision: | | 2 | |

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| Medical Device | Unigloves ZERO Nitrile 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 |

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| Manufacturer | **Unigloves Arzt- & Klinikbedarf Handelsgesellschaft mbH**<br>Camp-Spich-Str. 71<br>53842 Troisdorf-Spich<br>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

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| 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 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:

- CE-PI-20231117-01-01-9A

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

The PPE is subject to the conformity assessment procedure module C2 under the supervision of the Notified Body 2834.

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| Applied harmonised standards, national standards or other normative documents | EN ISO 21420:2020, EN ISO 374-1:2016 + A1:2016/<br>Type B – Test chemical Sodium hydroxide 40%, Hydrogen peroxide 30%, Ammonium hydroxide 25%<br><br>EN ISO 374-4:2019, EN ISO 374-5:2016 |
| Notified Body | CCQS Certification Services Limited (Kennnummer 2834)<br>Block 1 Blanchardstown Corporate Park, Ballycoolin Road,<br>D15 AKK1<br>Ireland |
| Certificates issued | CE-PI-20231117-01-01-9A valid until 14.12.2028 |
| EU Declaration is valid until | 02.06.2028 |

Troisdorf, 29.09.2025

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Dr. Sandra Heuser

*Person responsible*

*for regulatory compliance*

| Article number | Product description | 6 / XS | 7 / S | 8 / M | 9 / L | 10 / XL |
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| GM005* | Unigloves ZERO | GM0051 | GM0052 | GM0053 | GM0054 | GM0055 |