Product Family Examination Gloves

Medical Device	Unigloves Nitrile Examination Gloves
Catalogue number	See annex to the declaration of conformity
Basic UDI-DI according to Part C of Annex VI	426050314370R3
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

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 certificate number 2777/22896-01/E00-00.

The PPE is subject to the conformity assessment procedure module C2 under the supervision of the Notified Body 2777.

Applied harmonised standards, national standards or other normative documents	EN ISO 21420:2020, EN ISO 374-1:2016 + A1:2018/ Type B – Tested chemical n-Heptane, Hydrogen Peroxide 30%, Formaldehyde 37%, EN ISO 374-4:2019, EN ISO 374-5:2016
Notified Body	**Notified Body 2777** SATRA Technology Europe Limited, Bracetown Business Park, Clonee D15YN2P Ireland
Certificates issued	EC certificate 2777/22896-01/E00-00 valid until 22.11.2027
EU Declaration is valid until	02.06.2025

Troisdorf, 22.01.2024

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Dr. Sandra Heuser
Person responsible
for regulatory compliance

Annex to the Declaration of Conformity

Article No.	Description	Size
1112	Unigloves FORMAT® BLUE 300	S
1113	Unigloves FORMAT® BLUE 300	M
1114	Unigloves FORMAT® BLUE 300	L
1115	Unigloves FORMAT® BLUE 300	XL
1116	Unigloves FORMAT® BLUE 300	XXL
GM0071	Unigloves STRONGHOLD+®	XS
GM0072	Unigloves STRONGHOLD+®	S
GM0073	Unigloves STRONGHOLD+®	M
GM0074	Unigloves STRONGHOLD+®	L
GM0075	Unigloves STRONGHOLD+®	XL