UNIGLOVES®

CE Declaration of Conformity

according to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices

Medical Device	**UNIGLOVES Safetec Examination Gloves**
Article number	**1301, 1302, 1303, 1304, 1305**
Basic UDI-DI according to Annex VI Part C	4260503143710R3
Intended Use	The non-sterile disposable examination gloves are used to protect patients, users or third parties against diseases and provide temporal protection against bacteria, fungi 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, Rule 1 and 5	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 above-mentioned medical devices in accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council of 05 April 2017 concerning medical devices.

UNIGLOVES Arzt- & Klinikbedarf Handelsgesellschaft mbH hereby declares that medical devices covered by this declaration comply with this Regulation and, where applicable, other relevant Union legislation providing for the drawing up of an EU declaration of conformity.

Conformity for the above medical devices is in accordance with the applicable specifications:

EN 455-1:2000	
EN 455-2:2015	
EN 455-3:2015	
EN 455-4:2009	
Common specification	None

Chosen conformity assessment procedure	Technical File according to annex II und annex III

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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 certificate number 2777/12331-01/E01-02.

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 420:2003 + A1:2009, EN ISO 374-1:2016 / Type C – Tested chemical 40% Sodium hydroxide, EN ISO 374-4:2013, EN ISO 374-5:2016

Conformity assessment body	**Notified Body 2777** SATRA Technology Europe Bracetown Business Park Clonee D15 YN2P Ireland

Troisdorf, 05.10.2021

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CEO, Sebastian Schuster