



In application of the Regulation (EU) 2016/425 of 9 March 2016 concerning the harmonization of the Member States legislation relative to personal protective equipment, Centexbel Notified body 0493 authorized by the FPS Economy (Federal Public Services) has issued the following:

EU TYPE EXAMINATION CERTIFICATE

Nr. 032/2018/0654.02

This EU Type examination certificate is valid until 21 Apr 2023

to: **Ansell Healthcare Europe nv, Brussel**

for: **The Gloves Gammex® Non-Latex**

The personal protective equipment above mentioned satisfies the applicable essential safety requirements of the Regulation (EU) 2016/425.

For the argumentation, the following standards are used:

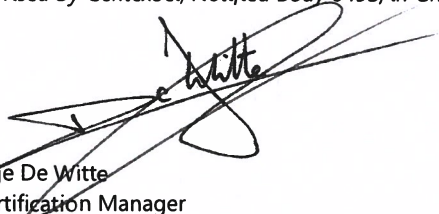
EN 420:2003+A1:2009	Protective gloves - General requirements and test methods
EN 421:2010	Protective gloves against ionizing radiation and radioactive contamination
EN ISO 374-1:2016	Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks
EN ISO 374-5:2016	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risk

This is PPE of category III, subject to regular checks in accordance with article 19 of the European PPE Regulation. In agreement with the manufacturer's choice audits of the production process shall be carried out to assess the Conformity of type (Module D). The manufacturer must be able, on request, to present the audit report. A first audit shall be performed at the latest on 31 Dec 2019 and at least be repeated with intervals of one year.

This declaration applies to the equipment as submitted in the type testing and described in the manufacturer's technical documentation (As described in 2016/425 Annex III) that is registered with number 10310.

This certificate has been drawn up in accordance with the general certification regulation of Centexbel which is available via <https://www.centexbel.be>

Issued by Centexbel, Notified Body 0493, in Ghent, on 10 Apr 2018
(Revised by Centexbel, Notified Body 0493, in Ghent, on 24 Nov 2020)


Inge De Witte
Certification Manager

Attached: 1 Annex



ANNEX

EU TYPE EXAMINATION CERTIFICATE Nr. 032/2018/0654.02

1. Applicant

Ansell Healthcare Europe nv
Riverside Business Park Spey House
Internationalelaan 55
1070 Brussel
Belgium

2. Description

EN 421:2010



EN ISO 374-1 / Type A



K L M N P T

EN ISO 374-5:2016



VIRUS

3. Materials and accessories

Gloves

- Gammex® Non-Latex



4. Technical documentation

Summary test results

EN 420:2003+A1:2009

Gloves

Gammex® Non-Latex

Method	Description	Result	Class
EN 1413	pH - textile	PASS	
EN 14362-1	AZO dyes for colored gloves	PASS	
EN 420 length	Length	PASS	
EN 420 dexterity	Dexterity	PASS	Level 5
1149-1 / 1149-2 / 1149-3	Electrostatic properties	/	/

EN 421:2010

Gloves

Gammex® Non-Latex

Method	Description	Result	Class
EN 374-2	Penetration	PASS	
EN 374-3	Permeation K	PASS	Level 6
EN 374-3	Permeation L	PASS	Level 3
EN 374-3	Permeation M	PASS	Level 6
EN 374-3	Permeation N	PASS	Level 3
EN 374-3	Permeation P	PASS	Level 6
EN 374-3	Permeation T	PASS	Level 6
EN 420 dexterity	Dexterity	PASS	Level 5
EN 421 4.3 method 5.1	Attenuation efficiency and uniformity of distribution	/	/
EN 388	Mechanical requirements	Dexterity is the most important parameter	/

EN ISO 374-1:2016

Gloves

Gammex® Non-Latex

Method	Description	Result	Class
EN 374-2	Penetration	PASS	
EN 16523-1	Permeation K	PASS	Level 6
EN 16523-1	Permeation L	PASS	Level 3
EN 16523-1	Permeation M	PASS	Level 6
EN 16523-1	Permeation N	PASS	Level 3
EN 16523-1	Permeation P	PASS	Level 6
EN 16523-1	Permeation T	PASS	Level 6
EN374-4	Degradation K	PASS	
EN374-4	Degradation L	PASS	
EN374-4	Degradation M	PASS	
EN374-4	Degradation N	PASS	
EN374-4	Degradation P	PASS	
EN374-4	Degradation T	PASS	
Type of glove		PASS	Type A

EN ISO 374-5:2016

Gloves

Gammex® Non-Latex

Method	Description	Result	Class
EN 374-2	Penetration	PASS	
ISO 16604 Proc. B	Protection against viruses	PASS	

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Description/Picture of article

Article **The Gloves Gammex® Non-Latex**



The above picture is a general picture of the article. Possible variations of the above article can be present in the technical file.

Note :

Any modification in material, design, or other technical features must be brought to the attention of the Notified Body.