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. 032/2022/0216

This EU Type examination certificate is valid until 15 Feb 2027

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

for: **The Gloves GAMMEX® Latex Underglove**

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 ISO 21420:2020	*Protective gloves - General requirements and test methods*
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 2023 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 the Regulation (EU) 2016/425 Annex III) that is registered with number 14033.

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 15 Feb 2022

Inge De Witte
Certification Manager

Attached: 1 Annex

INRICHTING ERKEND BIJ TOESPASSING VAN DE BESLUITWET VAN 30 JANUARI 1947 / ETABLISSEMENT RECONNU PAR APPLICATION DE L'ARRÊTE-LOI DU 30 JANVIER 1947

BELAC 056-PROD

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Digitally signed by Centexbel

ANNEX

EU TYPE EXAMINATION CERTIFICATE Nr. 032/2022/0216

1. Applicant

Ansell Healthcare Europe NV/SA
Riverside Business Park
Block J Boulevard International 55
1070 Brussels
Belgium

2. Description

EN ISO 374-1 / Type B



K P T

EN ISO 374-5:2016



VIRUS

3. Materials and accessories

Gloves

- GAMMEX® Latex Underglove

INRICHTING ERKEND BIJ TOESPASSING VAN DE BESLUITWET VAN 30 JANUARI 1947 / ETABLISSEMENT RECONNU PAR APPLICATION DE L'ARRÊTE-LOI DU 30 JANVIER 1947

4. Technical documentation

Summary test results

EN ISO 21420:2020 Gloves **GAMMEX® Latex Underglove**

Method	Description	Result	Class
ISO 3071	pH - textile	PASS	
EN 14362-1	AZO dyes for colored gloves	PASS	
ISO/TS 16190	Polycyclic aromatic hydrocarbons (PAHs)	PASS	
EN 16778	Dimethylformamide (DMFa)	/	/
EN ISO 21420 length	Length	PASS	
1149-1 / 1149-2 / 1149-3 or EN 16350	Electrostatic properties	/	/
EN ISO 21420 6.2 dexterity	Dexterity	PASS	Level 5
ISO 14268 leather / ISO 11092 textile	Water vapour transmission	/	/
ISO 20344:2011 leather	Water vapour absorption	/	/

EN ISO 374-1:2016 Gloves **GAMMEX® Latex Underglove**

Method	Description	Result	Class
EN 374-2	Penetration	PASS	
EN 16523-1	Permeation K	PASS	Level 6
EN 16523-1	Permeation P	PASS	Level 6
EN 16523-1	Permeation T	PASS	Level 6
EN 374-4	Degradation K	PASS	
EN 374-4	Degradation P	PASS	
EN 374-4	Degradation T	PASS	
Type of glove		PASS	Type B

EN ISO 374-5:2016 Gloves **GAMMEX® Latex Underglove**

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

INRICHTING ERKEND BIJ TOEPASSING VAN DE BESLUITWET VAN 30 JANUARI 1947 / ETABLISSEMENT RECONNU PAR APPLICATION DE L'ARRÊTE-LOI DU 30 JANVIER 1947

Description/Picture of article

Article **The Gloves GAMMEX® Latex Underglove**



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.

INRICHTING ERKEND BIJ TOESPASSING VAN DE BESLUITWET VAN 30 JANUARI 1947 / ETABLISSEMENT RECONNU PAR APPLICATION DE L'ARRÊTE-LOI DU 30 JANVIER 1947