



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. 032/2022/0253**

**This EU Type examination certificate is valid until 22 Feb 2027**

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

for: **The Gloves ENCORE® Latex Ortho & GAMMEX® Latex Ortho**

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:

<i>EN ISO 21420:2020</i>	<i>Protective gloves - General requirements and test methods</i>
<i>EN 388:2016+A1:2018</i>	<i>Protective gloves against mechanical risks</i>
<i>EN ISO 374-1:2016</i>	<i>Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks</i>
<i>EN ISO 374-5:2016</i>	<i>Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risk</i>

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 14050.

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 22 Feb 2022

  
Inge De Witte  
Certification M

Attached: 1 Annex



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Digitally signed by Centexbel



## ANNEX

### EU TYPE EXAMINATION CERTIFICATE Nr. 032/2022/0253

#### 1. Applicant

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

#### 2. Description

EN 388:2016+A1:2018



0010X

EN ISO 374-1 / Type B



KPT

EN ISO 374-5:2016



VIRUS

#### 3. Materials and accessories

##### Gloves

- ENCORE® Latex Ortho & GAMMEX® Latex Ortho



#### 4. Technical documentation

##### Summary test results

EN ISO 21420:2020

Gloves

**ENCORE® Latex Ortho & GAMMEX® Latex Ortho**

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 388:2016+A1:2018

Gloves

**ENCORE® Latex Ortho & GAMMEX® Latex Ortho**

Method	Description	Result	Class
EN 13594:2015 §6.9	Impact Test	/	/
EN 388 6.1	Abrasion resistance	/	Level 0
EN 388 6.2	Cut resistance	/	Level 0
EN 388 6.4	Tear resistance	PASS	Level 1
EN 388 6.5	Puncture resistance	/	Level 0
ISO 13997 6.3	Cut resistance	/	X

EN ISO 374-1:2016

Gloves

**ENCORE® Latex Ortho & GAMMEX® Latex Ortho**

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

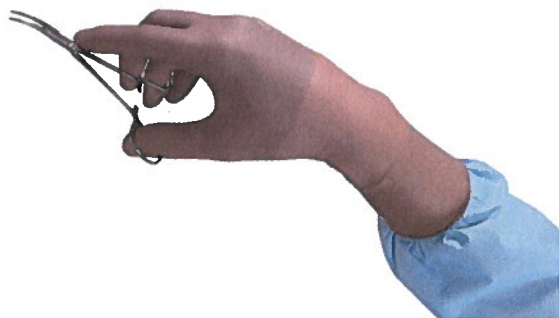
Gloves

**ENCORE® Latex Ortho & GAMMEX® Latex Ortho**

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

## Description/Picture of article

Article **The Gloves ENCORE® Latex Ortho & GAMMEX® Latex Ortho**



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.