



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. 032/2018/2060

This EU Type examination certificate is valid until 12 Apr 2024

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

for: **The Gloves AlphaTec® 15-554**

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 388:2016	Protective gloves against mechanical risks
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

If there is a former EC Type examination certificate according to the Directive 89/686/EEC this certificate remains valid until 21 April 2023 unless it expires before that date, for products that were manufactured before the issuance of this new EU Type examination certificate according to the Regulation (EU) 2016/425.

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 supervised product checks at random intervals shall be carried out to assess the quality of the final product (Module C2). The manufacturer must be able, on request, to present the test report of this quality control check. A first quality control check shall be performed at the latest on 31 Dec 2020 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 10679.

Issued by Centexbel, Notified Body 0493, in Ghent, on 12 Apr 2019



Inge De Witte
Certification Manager

Attached: 1 Annex



ANNEX

EU TYPE EXAMINATION CERTIFICATE Nr. 032/2018/2060

1. Applicant

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

2. Description

EN 388:2016



3 1 2 1 A

EN ISO 374-1 / Type A



B C D F I J

EN ISO 374-5



3. Materials and accessories

Gloves

- AlphaTec® 15-554



4. Technical documentation

Summary test results

EN 420:2003+A1:2009 Gloves **AlphaTec® 15-554**

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

EN 388:2016 Gloves **AlphaTec® 15-554**

Method	Description	Result	Class
EN 13594:2015 §6.9	Impact Test	/	/
EN 388 6.1	Abrasion	PASS	Level 3
EN 388 6.2	Cut resistance	PASS	Level 1
EN 388 6.4	Tear resistance	PASS	Level 2
EN 388 6.5	Puncture resistance	PASS	Level 1
ISO 13997 6.3	Cut resistance	PASS	Level A

EN ISO 374-1:2016 Gloves **AlphaTec® 15-554**

Method	Description	Result	Class
EN 374-2	Penetration	PASS	
EN 16523-1	Permeation B	PASS	Level 3
EN 16523-1	Permeation C	PASS	Level 5
EN 16523-1	Permeation D	PASS	Level 6
EN 16523-1	Permeation F	PASS	Level 6
EN 16523-1	Permeation I	PASS	Level 6
EN 16523-1	Permeation J	PASS	Level 6
EN 374-4	Degradation B	PASS	
EN 374-4	Degradation C	PASS	
EN 374-4	Degradation D	PASS	
EN 374-4	Degradation F	PASS	
EN 374-4	Degradation I	PASS	
EN 374-4	Degradation J	PASS	
Type of glove		PASS	Type A

EN ISO 374-5:2016 Gloves **AlphaTec® 15-554**

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

Description/Picture of article

Article **The Gloves AlphaTec® 15-554**



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.