



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. 032/2018/1742

This EU Type examination certificate is valid until 04 Oct 2023

to: **Ansell Healthcare Europe nv, Brussel**
for: **The Gloves AlphaTec® 87-900 & Ixell X Spirit**

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:

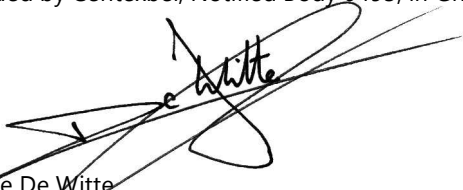
EN 421:2010	Protective gloves against ionizing radiation and radioactive contamination
EN 388:2016	Protective gloves against mechanical risks
EN ISO 374-1:2016	Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks
EN ISO 374-5:2016	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risk
EN 420:2003+A1:2009	Protective gloves - General requirements and test methods

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 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 11279.

Issued by Centexbel, Notified Body 0493, in Ghent, on 04 Oct 2018


Inge De Witte
Certification Manager

Attached: 1 Annex



ANNEX

EU TYPE EXAMINATION CERTIFICATE Nr. 032/2018/1742

1. Applicant

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

2. Description

EN 421:2010



EN 388:2016



2 1 2 0 A

EN ISO 374-1 / Type A



A K L N P T

EN ISO 374-5



VIRUS



3. Materials and accessories

Gloves

- AlphaTec® 87-900 & Ixell X Spirit

4. Technical documentation

Summary test results

EN 420:2003+A1:2009 Gloves **AlphaTec® 87-900 & Ixell X Spirit**

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 **AlphaTec® 87-900 & Ixell X Spirit**

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

EN 388:2016 Gloves **AlphaTec® 87-900 & Ixell X Spirit**

Method	Description	Result	Class
EN 13594:2015 §6.9	Impact Test	/	/
EN 388 6.1	Abrasion	PASS	Level 2
EN 388 6.2	Cut resistance	PASS	Level 1
EN 388 6.4	Tear resistance	PASS	Level 2
EN 388 6.5	Puncture resistance	/	Level 0
ISO 13997 6.3	Cut resistance	PASS	Level A

EN ISO 374-1:2016 Gloves **AlphaTec® 87-900 & Ixell X Spirit**

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

EN ISO 374-5:2016 Gloves **AlphaTec® 87-900 & Ixell X Spirit**

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

Description/Picture of article

Article **The Gloves AlphaTec® 87-900 & Ixell X Spirit**



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.