

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. 032/2019/0046

This EU Type examination certificate is valid until 14 Jan 2024

to: Ansell Healthcare Europe nv, Brussel

for: The Gloves AlphaTec® 39-122 & 39-124

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:

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EN 420:2003+A1:2009	Protective gloves - General requirements and test methods
EN 407:2004	Protective gloves against thermal risks (heat and/or fire)
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 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 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 11570.

Issued by Centexbel, Notified Body 0493, in Ghent, on 14 Jan 2019

Inge De Witte

Certification Manager

Attached: 1 Annex



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