



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. 032/2021/0781

This EU Type examination certificate is valid until 18 Aug 2026

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

for: **The Gloves AlphaTec® 58-335**

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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| <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 21420:2020</i> | <i>Protective gloves - General requirements and test methods</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> |
| <i>EN 388:2016+A1:2018</i> | <i>Protective gloves against mechanical risks</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 2022 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 13554.

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 18 Aug 2021



Inge De Witte
Certification Manager

Attached: 1 Annex