

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. 032/2019/1749

This EU Type examination certificate is valid until 26 Nov 2024

to: Ansell Healthcare Europe nv, Brussel for: The Gloves AlphaTec® Solvex® 37-185

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

ISO 1889:2019 Protective gloves for pesticide operators and re-entry workers - Performance requirements

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 12324.

Issued by Centexbel, Notified Body 0493, in Ghent, on 26 Nov 2019

large De Witte Certification Manager

Attached: 1 Annex

