

# EU Type-Examination Certificate

## Regulation on Personal Protective Equipment (Module B) Certificate No.: 0200-PPE-06312 version 1

FORCE Certification A/S (EU-notified body number 0200) has in accordance with Regulation (EU) 2016/425 of The European Parliament and of The Council of 9 March 2016, issued EU Type-Examination Certificate to:

Manufacturer: **Ansell Protective Solutions AB**  
**Arenagatan 8B**  
**SE-215 33 Malmö, Sweden**

For manufacturing the following personal protective equipment:

Type/Description: **Chemical protective clothing**

Model/Designation: **AlphaTec® LIGHT type TR (previously Trelchem)**

**To be used with positive pressure breathing apparatus. Use of AlphaTec® Mini Hood or SCBA Cover is recommended, alternatively permanently attached full face mask. Integral socks/booties in the suit material or attached PVC boots. Gastight PVC zipper. Bayonet ring system with attached AlphaTec® Scorio 08-354 neoprene rubber gloves.**

Applied standard(s): **EN 943-1:2015 + A1:2019,**  
**EN 14126:2003**

Performance level: **Gastight suit type 1b-B.**

Category: **III**

The examined sample of personal protective equipment is found to fulfill the relevant requirements of the applied standard(s) and to be in compliance with the applicable essential health and safety requirements of Regulation (EU) 2016/425. Documentation for observance of relevant requirements and the basis for the type-examination are described in the appendix to this certificate. The manufacturer shall inform FORCE Certification A/S of any contemplated changes.

This certificate can only be used in conjunction with a valid conformity assessment procedure according to Regulation (EU) 2016/425 module C2 or D.

Date of issue: **2019-04-24**

Date of expiry: **2024-04-24**



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**Philippa W. Osted**  
Certification Manager



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**Erik Bjarnov**  
Examiner

FORCE Certification A/S task No.: **119-22282.04** / Certificate ID: **06312**

This certificate will remain valid unless cancelled, revoked or expired, provided the conditions in the attached appendix are complied with, and that the equipment remains state of the art within its applicable field of service. Status of this certificate can be verified on [www.forcecertification.com](http://www.forcecertification.com). This EU Type-Examination Certificate is the property of FORCE Certification A/S. Extracts of this certificate may only be reproduced with a written permission from FORCE Certification A/S.

# Classification Annex to EU Type-Examination Certificate

## Regulation on Personal Protective Equipment (Module B)

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### AlphaTec® LIGHT material properties. Classification according to EN 14325:2018

Property	Class	Class requirements
Abrasion resistance (EN 530)	6	> 2000 cycles
Flex cracking resistance (ISO 7854:B)	6	>50 000 cycles
Flex cracking resistance at – 30 °C (ISO 7854:B)	6	> 4000 cycles
Tear resistance (EN ISO 9073-4)	4	> 60 N
Tensile strength (EN ISO 13934-1)	6	> 1000 N
Puncture resistance (EN 863)	3	> 50 N
Resistance to flame* (EN 13274-4:2001 method 3 modified)	2	1s in flame, leak tight afterwards
Seam strength (EN ISO 13935-2)	6	> 500 N
Closure/zipper strength (EN ISO 13935-2)	6	> 500 N

\* If resistance to flame is essential for the use of this product, specific testing should be performed depending on the intended use, e.g. EN ISO 14116.

### Additional tests not required in EN 943-1:2015 and EN 14325:2018.

Property	Value or class	Requirements
EN 1149-5:2008 Decay time t50	t <sub>50</sub> <0,16s	t <sub>50</sub> <4s

### Resistance to permeation by chemicals.

Chemical	Light suit	Light suit seam	PVC zipper	AlphaTec® Scorpio 08-354 glove	Dunlop PVC boot
Formaldehyde solution	6	6	6	6	6
Hydrochloric acid 37%	6	6	6	6	6
Sodium hydroxide 40%	6	6	6	6	6
Sulphuric acid 50 %	6	6	6	6	6

### Classification for protection against infective agents according to EN 14126:2003

Property	Class
Resistance to penetration by contaminated liquids under pressure (ISO16603 and ISO 16604)	6
Resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids (EN ISO 22610:2006)	6
Resistance to penetration by contaminated liquid aerosols (ISO/DIS 22611)	3
Resistance to penetration by contaminated solid particles (ISO 22612)	3

Date: 2019-04-24



Erik Bjarnov  
Examiner

# Appendix to EU Type-Examination Certificate

## Regulation on Personal Protective Equipment (Module B)

Certificate No.: DK-0200-PPE-**06312** version **1**  
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**Manufacturer:** **Ansell Protective Solutions AB**  
**Arenagatan 8B**  
**SE-215 33 Malmö, Sweden**

### Identification of personal protective equipment:

Type/Description: **Chemical protective clothing**

Model/Designation: **AlphaTec® LIGHT type TR**  
**(previously Trellechem)**

Size(s): **XXS - XXXL**

Applied standard(s): **EN 943-1:2015 + A1:2019,**  
**EN 14126:2003**

Performance level: **Gastight suit type 1a-B.**

Configuration/Options **Non-encapsulating suit to be used with positive pressure breathing apparatus. Use of AlphaTec® Mini Hood or SCBA Cover is recommended.**  
**PVC coated gastight zipper.**

**AlphaTec® Bayonet ring system with attached AlphaTec® Scorpio 08-354 chloroprene rubber gloves.**

**One AlphaTec® Exhaust valve on the chest.**

#### Options:

- permanently attached Dräger Panorama Nova EPDM or Interspiro Spiromatic or Fenzy Panoramisque full face mask.
- Reinforcements on elbows and knees

Category: **III**

Design: **Rear-entry, PVC coated gastight zipper, 805 mm long, positioned on the back, across the shoulders. It is protected by a splash protective flap.**  
**The suit colour is orange as standard**

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AlphaTec® LIGHT type TR suit with knee reinforcement option, boot version.



Detail of face seal



Detail showing the zipper position

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Detail showing AlphaTec® Bayonet ring glove attachment

### History:

Issue/change:	Certificate No.:	Certificate ID:	Issue date:
- Original certificate	DK-0200-PPE-06312 version 1	06312	2019-04-24

### Place(s) of Production:

Final assembly	Address
Ansell Protective Solutions Lithuania UAB	Pramones 5K, 72328 Taurage, Lithuania,

### List of sub-suppliers:

Component	Designation:	Supplied by:
- Gloves	AlphaTec® Scorpio 08-354	Ansell Healthcare Europe, Bruxelles, Belgium
- Boots	Dunlop Acifort A4422B1	Dunlop-Hevea, Netherlands
- Zipper	PVC coated	Dynat Verschlussstechnik, Germany
- Material	LIGHT, 510 g/m <sup>2</sup> APS part no K64 708 300	Low & Bonar GMBH/Mehler Technologies SIA, Germany
- Full face masks	Dräger Panorama Nova Interspiro Spiromatic Fenzy Panoramisque	Dräger Safety, Lübeck, DE Interspiro, Täby, SE Honeywell, FR

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### Documentation for observance of relevant requirements stated in the applied standard(s): EN 943-1:2015 + A1:2019

EN 943-1:2015	Test house	Report No.:
4.1 General		
4.2 Materials		
- Abrasion resistance	BTTG (2018)	60/01755/A
- Flex cracking resistance	FORCE Technology (2018)	118-21047.05d
- Flex cracking at -30 °C (optional)	FORCE Technology (2018)	118-21047.05d
- Trapezoidal tear resistance	BTTG (2018)	60/01755/A
- Tensile strength	BTTG (2018)	60/01755/A
- Puncture resistance	FORCE Technology (2013)	113-27778
	BTTG (2018)	60/01755/A
- Resistance to flame	BTTG (2018)	60/01755/B
	FORCE Technology (2018)	118-21047.05d
Resistance to permeation by chemicals (liquids and gases)		
- Material	ProQares (2017)	48728-54100
4.3 Seams, joins, and assemblages		
Strength		
- Material seam	FORCE Technology (2019)	119-22272.05
- Closure strength (Zipper)	FORCE Technology (2019)	119-22272.05
Permeation		
- Material seam	ProQares (2016)	34862-33723,
	ProQares (2019)	69684-68546
4.4 Strength of detachable joins	FORCE Technology (2018)	118-21047.06e
4.5 Permeation requirement for closure	ProQares (2016)	34862-33723,
	ProQares (2019)	69684-68546
<u>5 Requirements for the whole suit</u>		
5.1 General	BTTG (2018)	60/01755/A
	FORCE Technology (2019)	119-22272.02
	Applicant	Technical File (DoI, Label, IFU)
5.2 Compatibility with other equipment	FORCE Technology (2019)	119-22272.02
5.3 Conditioning to simulate storage conditions	FORCE Technology (2019)	119-22272.02
5.4 Leak tightness (static inflation test)	FORCE Technology (2019)	119-22272.02
5.5 Total inward leakage test	Dekra (2017)	9260/17
5.6 Visor		Not Applicable
5.7 Face piece for suits without integral visor		
- Jet test	FORCE Technology (2018)	118-21047.10
- - mini Hood	FORCE Technology (2009)	108-32677.05b

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5.8 Pass-through		Not Applicable
5.9 Airline supply system		Not Applicable
5.10 Exhaust assembly	FORCE Technology (2017)	117-20950.16
	FORCE Technology (2016)	115-24375.01
5.11 Pressure in chemical protective suit	FORCE Technology (2018)	118-21047.06e
5.12 External ventilating hose		Not Applicable
5.13 Air flow rate of breathing air and/or ventilating air supply		Not Applicable
5.14 Carbon dioxide content of inhalation air		Not Applicable
5.15 Noise associated with air supply to suit		Not Applicable
5.16 Practical Performance	FORCE Technology (2019)	119-22272.02

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#### Gloves

AlphaTec® Scorpio 08-354	Centexbel (2008)	EC Certificate 03206165
- permeation properties	ProQares (2016, 2018) Centexbel (2014)	34862-33723, 60652-58242 14.0293.01
- mechanical resistance	Centexbel (2008)	EC Certificate 03206165

#### Boots

Dunlop Acifort PVC boots	CTCP (2017)	EC Certificate CE-1775-49/17
- permeation properties	ProQares (2018, 2016)	60627-58355, 34862-33723

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**Partial conclusion:** The requirements stated in the applied standards are fulfilled for the relevant test clauses and classification(s)/performance level(s).

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### Documentation for observance of relevant requirements stated in the applied standard(s): **EN 14126:2003**

Requirement:	Test house	Report No.:
4.1.1 Cleaning and reprocessing	Centexbel (2017)	17.04412.00
4.1.2 and 4.1.3 mechanical and chemical requirements	See detailed list above under EN 943	
4.1.4.1 Resistance to penetration by contaminated liquids under pressure	Centexbel (2017)	17.04412.00
4.1.4.2 Resistance to penetration by infective agents due to mechanical contact with substances containing vcontaminated liquids	Centexbel (2017)	17.04412.00
4.1.4.3 Resistance to penetration by contaminated aerosols	Centexbel (2017)	17.04412.00
4.1.4.4 Resistance to penetration by contaminated solid particles	Centexbel (2017)	17.04412.00
4.2 Seams, Joins and assemblages	See detailed list above under EN 943	
4.3 Whole suit requirements	See detailed list above under EN 943	

**Partial conclusion:** The requirements stated in the applied standards are fulfilled for the relevant test clauses and classification(s)/performance level(s).

### Documentation for observance of relevant requirements stated in other the harmonized standards

Electrical surface resistance, EN 1149-1:2006	CENTEXBEL (2018)	Analysis report Nr. 18.02121.02
Electrostatic charge decay, EN 1149-3:2004	CENTEXBEL (2018)	Analysis report Nr. 18.02121.02



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### Further documentation for observance of relevant requirements stated in Annex III of Regulation (EU) 2016/425:

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- Risk assessment	Dated 2019-04-08
- List of applicable EHSR	Dated 2019-04-08
- Drawings	363039-333, 2019-02-22
- Description of quality system	VP11-A6-F001A, 2019-02-22
- User information and marking	Chemical Protective Suits, Instructions for Use ed. 1902 - AlphaTec® LGHT type TR Label K78102463 (1902)
- Declaration of innocuousness	DoI dated 2019-04-08
List of materials and sub-suppliers	See above

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The user information and marking was assessed in English. The manufacturer is obligated to supply the user information and marking in the official language(s) of the country in which the equipment is placed on the market.

### Conclusion

Based on the above-mentioned attestation it can be concluded that the personal protective equipment, AlphaTec® LIGHT type TR, meets the conditions of an EU type-examination in accordance with Regulation (EU) 2016/425 module B.

FORCE Certification A/S task No.: 119-22282.04  
Date: 2019-04-24



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**Erik Bjarnov**  
Examiner