FOOD DECLARATION OF PRODUCT COMPLIANCE

the Authorised Representative, established in the European Community:

ANSELL HEALTHCARE EUROPE N.V.
RIVERSIDE BUSINESS PARK, BLOCK J
BOULEVARD INTERNATIONAL 55
B-1070 BRUSSELS

declares that the glove described hereafter:

AlphaTec® 62-201

belonging to the "Elastomers and Rubber" category (for more detailed information on product composition please consult the Ansell Technical Datasheet)

is in conformity with the following provisions:

the EC-regulation 1935/2004 and the EC-regulation 2023/2006 related to Good Manufacturing Practices (GMP) for Materials and Articles intended to come in contact with Foodstuffs (for more detailed information please also consult Ansell GMP Food Declaration).

All ingredients, starting monomers, additives used in manufacturing this glove comply with:
- any positive list
- any relevant SML(Specific Migration Limit) or restrictions as specified in the applicable EU-28 food legislations.

France: Arrêté du 9 novembre 1994, relatif aux matériaux et objets en caoutchouc au contact des denrées, produits et boissons alimentaires

Italy: D.M. 21/03/1973 Disciplina igienica degli imballaggi, recipienti, utensili, destinati a venire in contatto con le sostanze alimentari o con sostanze d'uso personale

Germany: BfR Empfehlung XXI (2011) Bedarfsgegenstände auf Basis von Natur- und Synthesekautschuk

Netherlands: Regeling Verpakkingen en Gebruiksartikelen (Warenwet), Hoofdstuk III, Rubberproducten Verpakkingen

Czech Republic: Vyhláška č. 38/2001 Sb. (Consolidated 2009-5-15) Annex 07: Elastomers and rubber products - list of materials

Slovakia: Výnos MPSR a MZSR z 9. júna 2003 č. 1799/2003 - 100, Annex 10

United Kingdom: FDA Code of Federal Regulations, Title 21, Part 177, section 2600 (21 CFR 177.2600) - Rubber articles intended for repeated use

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Ansell

For compliance in countries outside of the EU-28 or for more information, please contact Ansell at: info@eu.ansell.com

Global migration data:

Type of foodstuffs - Testing conditions	Aqueous food	Alcoholic food	Acidic food	Fatty food correction factor 1	Fatty food correction factor 2	Fatty food correction factor 3	Fatty food correction factor 4	Fatty food correction factor 5
2 hours/temp. 40°C	<10 mg/dm2	<10 mg/dm2	<10 mg/dm2	>10 mg/dm2	>10 mg/dm2	>10 mg/dm2	<10 mg/dm2	<10 mg/dm2
10min/40°C	<10 mg/dm2	<10 mg/dm2	<50 mg/dm2					

Analytical tolerance for aqueous, alcoholic and acidic food simulant is 2mg/dm2 and for fatty food simulant is 3mg/dm2.

Conclusions:

- As per French & Italian legislation: not suitable for contact with fatty food with a correction factor 1, 2 and 3
- No other restrictions apply

Guido Van Duren
Director – Regulatory Affairs PPE Products
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