

FOOD DECLARATION OF PRODUCT COMPLIANCE

The Business Operator, established in the European Community:

**ANSELL HEALTHCARE EUROPE N.V. RIVERSIDE BUSINESS PARK, BLOCK J
BOULEVARD INTERNATIONAL 5 5B-1070 BRUSSELS**

declares that the glove described hereafter:

AlphaTec® 04-004

belonging to the "Plastic" category, is in conformity with the following provisions:

- Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food
- Regulation (EC) No 2023/2006 on Good Manufacturing Practices (GMP) for materials and articles intended to come into contact with foodstuffs
- Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, including all its amendments
- Regulation (EU) 2025/351, amending Regulation (EU) No 10/2011 and Regulation (EC) No 2023/2006

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

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Global migration data:

Type of foodstuffs – Testing conditions	Aqueous food	Alcoholic food	Acidic food	Fatty food correction factor ¹ Simulant used: Ethanol 95%/Isooctane	Fatty food correction factor ² Simulant used: Ethanol 95%/Isooctane	Fatty food correction factor ³ Simulant used: Ethanol 95%/Isooctane	Fatty food correction factor ⁴ Simulant used: Ethanol 95%/Isooctane	Fatty food correction factor ⁵ Simulant used: Ethanol 95%/Isooctane
2 hours/temp. 40° C	< 10 mg/dm ²	< 10 mg/dm ²	< 10 mg/dm ²	> 10 mg/dm ²	> 10 mg/dm ²	> 10 mg/dm ²	> 10 mg/dm ²	> 10 mg/dm ²
10min/40° C	< 10 mg/dm ²	< 10 mg/dm ²	< 10 mg/dm ²					

Analytical tolerance for aqueous, alcoholic and acidic food simulant is 1mg/dm² and for fatty food simulant is 3mg/dm² as per EN 1186.

Storage instruction: Keep away from direct sunlight; store in a cool dry place and keep in the original packaging. Keep away from ozone sources. If gloves are properly stored, as indicated above, they won't lose their performances and won't change the glove characteristics significantly. If gloves could be affected by ageing or storage, the expiry date is mentioned on the packaging materials.



Guido Van Duren
Director – Regulatory affairs
Ansell

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