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® 23-200

Formerly known as VersaTouch® 23-200

belonging to the "Plastic" category

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 food legislations.

COMMISSION REGULATION (EU) No 10/2011 on plastic materials and articles intended to come into contact with food and all its amendments.

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Global migration data:

Type of foodstuffs - Testing conditions	Aqueous food *Simulant used: Distilled Water*	Alcoholic food *Simulant used: Ethanol 10%*	Acidic food *Simulant used: Acetic acid 3%*	Fatty food correction factor 1 *Simulant used: Olive oil*	Fatty food correction factor 2 *Simulant used: Olive oil*	Fatty food correction factor 3 *Simulant used: Olive oil*	Fatty food correction factor 4 *Simulant used: Olive oil*	Fatty food correction factor 5 *Simulant used: Olive oil*
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	< 10 mg/dm²					

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
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