## 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 55 B-1070 BRUSSELS

declares that the glove described hereafter:

AlphaTec® 58-001 ESD

## Ansell Healthcare Europe N.V.

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## Global migration data:

| Type of foodstuffs<br>-<br>Testing conditions | Aqueous food                      | Alcoholic food                | Acidic food                      | Fatty food<br>correction factor<br>1 | Fatty food correction factor 2 | Fatty food correction factor | Fatty food<br>correction factor<br>4 | Fatty food correction factor 5 |
|---|-----------------------------------|-------------------------------|----------------------------------|--------------------------------------|--------------------------------|------------------------------|--------------------------------------|--------------------------------|
|   | Simulant used:<br>Distilled Water | Simulant used:<br>Ethanol 15% | Simulant used:<br>Acetic acid 3% | Simulant used:<br>Olive oil          | Simulant used:<br>Olive oil    | Simulant used:<br>Olive oil  | Simulant used:<br>Olive oil          | Simulant used:<br>Olive oil    |
| 2 hours/temp. 40°C                            | < 8 mg/dm <sup>2</sup>            | < 8 mg/dm²                    | > 8 mg/dm <sup>2</sup>           | < 8 mg/dm <sup>2</sup>               | < 8 mg/dm <sup>2</sup>         | < 8 mg/dm <sup>2</sup>       | < 8 mg/dm <sup>2</sup>               | < 8 mg/dm²                     |
| 10min/40°C                                    | < 10<br>mg/dm²                    | < 10<br>mg/dm <sup>2</sup>    | < 10<br>mg/dm <sup>2</sup>       | < 10<br>mg/dm <sup>2</sup>           | < 10<br>mg/dm²                 | < 10<br>mg/dm <sup>2</sup>   | < 10<br>mg/dm <sup>2</sup>           | < 10<br>mg/dm²                 |

Analytical tolerance for aqueous, alcoholic and acidic food simulant is 1mg/dm<sup>2</sup> and for fatty food simulant is 3mg/dm<sup>2</sup> 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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