

Ansell Healthcare Europe N.V.

Riverside Business Park, Block J
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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:

HyFlex® 11-300

belonging to the "Textile" 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.

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

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**ISO 9002 Certificate
Number FM 40130**

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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/temp.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:

No restrictions apply to any of the foodstuffs' categories in the EU-28.

Guido Van Duren

Director – Global Regulatory Affairs
PPE Products
Ansell

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