



FEARLESS PERFORMANCE®

## EC DECLARATION OF COMPLIANCE

### FOOD-CONTACT MATERIALS

#### Granberg disposable gowns art. 210.0085

is in compliance with FOR 1993-12-21 nr 1381: Forskrift om materialer og gjenstander i kontakt med næringsmidler (as amended), with Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food (as amended), and with Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (as amended).

With reference to Regulation (EU) No 10/2011, Annex III and Annex V for the selection of food simulants and test conditions, and to EN 1186:2002 for the selection of test methods, this product has been subjected to and has passed the following tests as a single-use article:

Food Simulant	Food Simulant Abbreviation	Testing Conditions	Overall migration
Ethanol 10 % (v/v)	Food simulant A	30 min at 40 °C	Pass
Acetic acid 3 % (w/v)	Food simulant B	30 min at 40 °C	Pass
Vegetable oil alternatives:	Food simulant D2	30 min at 40 °C	Pass
Ethanol 95 %			
Iso-octane			

The specific migration of substances (Aluminium, Ammonium, Antimony, Arsenic, Barium, Cadmium, Calcium, Chromium, Cobalt, Copper, Europium, Gadolinium, Iron, Lanthanum, Lead, Lithium, Magnesium, Manganese, Mercury, Nickel, Potassium, Sodium, Terbium, Zinc) were assessed after extraction in 3% acetic acid for 30 minutes at 40°C and were found to meet with the requirements in Commission Regulation (EU) No. 10/2011, Annex II.

No dual-use additives (DUA) were used to produce Granberg disposable gowns art. 210.0085.



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According to Commission Regulation (EU) No 10/2011 of 14 January 2011 as amended <sup>1</sup>:

For tests to demonstrate compliance with the overall migration limit food simulants shall be chosen as set out in Table 3:

Table 3

Food simulant assignment for demonstrating compliance with the overall migration limit

Foods covered	Food simulants in which testing shall be performed
all types of food	1. distilled water or water of equivalent quality or food simulant A; 2. food simulant B; and 3. food simulant D2.
all types of food except for acidic foods	1. distilled water or water of equivalent quality or food simulant A; and 2. food simulant D2.
all aqueous and alcoholic foods and milk products with a pH $\geq$ 4,5	food simulant D1
all aqueous and alcoholic foods and milk products with a pH < 4,5	food simulant D1 and food simulant B
all aqueous foods and alcoholic foods up to an alcohol content of 20 %	food simulant C
all aqueous and acidic foods and alcoholic foods up to an alcohol content of 20 %	1. food simulant C; and 2. food simulant B.

Conclusion: The disposable gowns are suitable to be used with all types of food.

These disposable gowns have been manufactured according to the requirements of Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food (as amended).

Ole Marthon Granberg  
Managing Director

Date: 24.10.2022

<sup>1</sup> Amended and corrected by Commission Regulation (EU) 2017/752 of 28 April 2017, Commission Regulation (EU) 2019/37 of 10 January 2019 and Commission Regulation (EU) 2020/1245 of 2 September 2020.