



Declaration of Compliance

Business Operator

Vikan North America Corporation
4735 W. 106th Street
Zionsville, IN 46077

Product name on web

6 Mil Gown, Large, 45" Length, Red

Item Number

86034

**Plastic Material**

Thermoplastic polyurethane (TPU)

Color masterbatch

Red

US FDA Compliance

All raw materials in this product are in compliance with FDA (Food and Drug Administration in the USA) 21 CFR parts 170 to 199.

The polymers and additives complies with FDA 21 CFR part 174, 175, 176, 177, 178, 181, 182, 184, or 186. Additives are cleared according to FDA 21 CFR Part 178 (Indirect food additives), are generally recognised as safe (GRAS), are prior-sanctioned food ingredients, or are cleared on basis of regulations for food additives of before 1958.

The pigments in the masterbatch are listed under FDA 21 CFR 178.3297 „Colorants for Polymers“.

The rubber raw material in the products are in compliance with FDA (Food and Drug Administration in the USA) CFR 177.2600

Food contact types

- Aqueous
- Acidic
- Alcoholic
- Fatty
- Dry

Food contact usage time and temperature

Any food contact conditions for up to 24 hr at 104 °F



General

Appropriate equipment decontamination will minimise the risk of microbial growth and cross contamination and will maximise the efficiency and durability of the equipment.

Equipment should be cleaned, disinfected and sterilised, as appropriate to its intended use, before use.

It is also important to clean, disinfect and sterilise equipment as appropriate after use, using the appropriate decontamination chemicals, concentrations, times and temperatures.

The product is suitable for repeated use under the conditions specified in this Declaration of Compliance. Reuse does not affect the product's compliance with applicable food contact regulations, provided it remains intact, undamaged, and is cleaned appropriately between uses.

Vikan A/S is registered with the Danish Veterinary and Food Administration (DVFA), and our mandatory Own Control System is subject to inspection by the DVFA.

We will make the relevant background documentation available to the competent authorities, at their request.

Date

2026-06-09

Made By

Marta Sztuka
Materials and Compliance Specialist