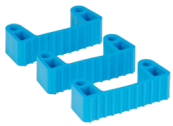
Declaration of Compliance

Business Operator	Vikan A/S Rævevej 1 DK-7800 Skive (+45) 96 14 26 00
Product Name	3 Spare part rubber bands for 1011x & 1013x, Blue
Item Number	10023
	
Plastic Material	Thermoplastic elastomer (TPE), 98 %

EU Compliance

Regulation (EU) No 10/2011	The monomers and additives used in the manufacture of this product are listed in Annex I to Regulation (EU) No 10/2011 of the European Parliament and of the Council of 14 January 2011 on plastic materials and articles intended to come into contact with food, as amended.
(EU) 2024/3190	The product has been manufactured and assessed in compliance with the criteria established by Regulation (EU) 2024/3190.
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.
Migration analysis plastics	Samples of the product, or a similar product made from identical plastic material, have been tested for overall migration according to the test conditions specified in (EU) 10/2011 for repeated use, and the article comply with the overall migration limit of 10 mg/dm² or 60 mg/kg. Test conditions for overall migration were OM0 (30 min at 40 °C) Food simulants used for overall migration were 50 % ethanol (simulant D1) and 3 % acetic acid (simulant B). Compliance with specific migration limits, and other restrictions, has been documented through testing, calculation or simulation.
Max ratio of food contact surface area to volume	2.1 dm²/100 ml

Food contact types

The product is suitable for contact with the following types of food under the intended and foreseeable conditions of use:

- ☑ Aqueous
- ☑ Acidic
- ☑ Alcoholic
- ☐ Fatty
- ☑ Dry

Food contact usage time and temperature

Any food contact conditions up to 40 °C for 30 min.

Non-food contact usage temperature

Minimum temperature:
Maximum temperature: 80

General

Equipment should be cleaned, disinfected and sterilised, as appropriate to it's 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.

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

Recommended sterilisation temperature (Autoclave): 121 °C

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

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.

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.

Date 2026-09-05

Made By

Marta Sztuka
Materials and Compliance Specialist