Declaration of Compliance

Business Operator	Vikan A/S Rævevej 1 DK-7800 Skive (+45) 96 14 26 00
Product name	Spare part Grip Band Module for 1011x, 1013x & HyGo, 5700x, White
Item Number	10035
	
Plastic Material	Polypropylene, 98 % Thermoplastic elastomer (TPE), 98 %

EU Compliance

Regulation (EC) No 1935/2004	In accordance with EU Commission Regulation no. 1935/2004 article 3, 11(5), 15 and 17 the product is intended for food contact. The product is marked with the "glass & fork" symbol on the packaging or on the product itself through moulding. 
AP(89)1	All pigments in the masterbatch comply with resolution AP 89(1)
Regulation (EC) No 2023/2006	The product is produced according to EU Commission Regulation no. 2023/2006 of 22. December 2006 on good manufacturing practices for materials and articles intended to come into contact with food (GMP).
Regulation (EU) No 10/2011	Monomers and intentionally added additives used to manufacture this product are listed in Annex I of Commission Regulation (EU) No. 10/2011 of 14. January 2011 on plastic materials and articles intended to come into contact with foodstuffs. Subsequent amendments up to (EU) 2024/3190 are included. Monomers and/or additives with specific migration limit (SML) are used. The substances with a SML will not migrate in quantities that will exceed the SML, under the specified conditions of use. Upon request we will supply relevant information regarding these substances on a confidential basis. Vikan A/S does not use multi-layer materials or articles with a functional barrier.
Regulations (EC) No 1333/2008 and (EC) No 1334/2008	This material contains intentionally added "dual use" additives for which restrictions or purity criteria are in place in accordance with Regulations (EC) 1333/2008 and (EC) 1334/2008. Upon request we will supply relevant information regarding these substances on a confidential basis.

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.
UK Compliance	The product complies with The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 No. 704
Danish Compliance	The product complies with the Danish consolidation Act no. 681 of 25/05/2020.
Japanese Compliance	All substances (polymers, monomers and additives) used in Vikan products comply with Article 18(3) of the Japanese Food Sanitation Act and are listed in Tables 1 and 2 of Appendix 1 of the Positive List.
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: 0 °C Maximum temperature: 80 °C

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.

Date 4/27/2025

Made By

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