

Declaration of Compliance

Business Operator	Vikan A/S Rævevej 1 DK-7800 Skive (+45) 96 14 26 00
Product Name	HyDrive Adaptor x 2 Pcs., Ø0.8", 2.2", Black
Item Number	87509
	
Plastic Material	Polyamide (nylon)
Color masterbatch	Black
Stainless steel	Stainless steel Grade 1.4301 (AISI 304)
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	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. 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.
(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.

The nylon material complies with the requirements of FDA (Food and Drug Administration in the USA) 21 CFR 177.1500 "Nylon resins".

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

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 OM7 (2 h at 175 °C)

Food simulants used for overall migration were 10 % ethanol (simulant A), 3 % acetic acid (simulant B) and olive oil (simulant D2).

Compliance with specific migration limits, and other restrictions, has been documented through testing, calculation or simulation.

Food contact types

- ☒ Aqueous
- ☒ Acidic
- ☒ Alcoholic
- ☒ Fatty
- ☒ Dry

Food contact usage time and temperature

Any food contact conditions up to 175 °C with aqueous, alcoholic, fatty and dry foods for up to 1 hour.

Any food contact conditions that include heating up to 70 °C for up to 2 hours, or up to 100 °C for up to 15 minutes with acidic foods.



**Non-food contact usage
temperature**

Minimum temperature: -20 °C
Maximum temperature:

General

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.

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

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.

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

2026-07-01

Made By

Marta Sztuka
Materials and Compliance Specialist