



## Declaration of Compliance

<b>Business Operator</b>	Vikan A/S Rævevej 1 DK-7800 Skive (+45) 96 14 26 00
<b>Description</b>	Flexible Handle, stainless steel, Ø5 mm, 755 mm, White
Item Number	53515
	
Plastic Material	Polypropylene, 97 %
Foaming agent	Chemical foaming agent, 1 %
Stainless steel	The stainless steel staple is made from stainless steel Grade 1.4301 (AISI 304) The stainless steel nipple is made from stainless steel Grade 1.4305 (AISI 303)
<b>EU Compliance</b>	
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.  The stainless steel comply with European Standard EN 10088 and the specific release limits (SRLs) set out in the Council of Europe guide: "Metals and alloys used in food contact materials and articles".  
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) 2019/1338 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.
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.
AP(89)1	All pigments in the masterbatch comply with resolution AP 89(1)



#### **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 polypropylene complies with FDA 21 CFR 177.1520 "olefin polymers".

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

The stainless steel in this product is in compliance with FDA (Food and Drug Administration in the USA) Food Code 2013 and is listed in NSF/ANSI 51-2014 on Food Equipment Materials

#### **Danish Compliance**

The product complies with the Danish consolidation Act no. 1248 of 30/10/2018.

#### **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, and the article comply with the overall migration limit of 10 mg/dm<sup>2</sup> or 60 mg/kg.

Test conditions for overall migration were OM2 (10 days at 40 °C)

Food simulants used for overall migration were 50 % ethanol (simulant D1), 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**

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 100 °C

#### **Non-food contact usage temperature**

Minimum temperature: -20 °C  
Maximum temperature: 100 °C

**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

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**

31/10/2019

**Made By**

Stine Lønnerup Bislev  
Hygiene and Compliance Manager