

## DECLARATION OF COMPLIANCE WITH FOOD CONTACT LEGISLATION

### 1. Company Identification

We, Digmesa AG, Keltenstrasse 31, 2563 Ipsach, Switzerland, declare that the article and materials thereof described hereunder and assembled at our headquarters and manufacturing site at once in Switzerland are compliant with the corresponding food contact requirements listed in the present document.

### 2. Description of the article

**Commercial name:** Flowmeter FHKSC

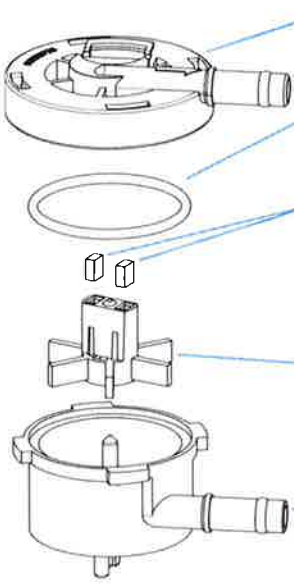
**Item numbers:** 932-95xx/Axxx, 932-95xx/Bxxx  
 974-95xx/Axxx, 974-95xx/Bxxx

**Description:** The FHKSC Flowmeter is a general-purpose device that has been specially designed for coffee machines that use vibratory pumps. The device is installed between the water container and the vibratory pump (on the suction side) and in this way prevents the measuring errors that arise during pulsating water flow caused by vibratory pumps.

**Picture of the article:**



**Product build-up of parts intended to come into contact with food:**

Product build-up	Part designation	Part number	Material type	Material formulation	Max. food contact area (cm <sup>2</sup> )
	Upper housing part	310-450x	Plastic PBT with 30-35% glass-fibre (GF)	A) Arnite TV4 270 B) Ultradur B4300 G6 FC Acqua	18.9
	O-Ring	350-0414	Elastomer VMQ	Pertec UP VMQ 70.501-01	2.64
	Magnets	480-0000	Ceramic Hard ferrite	A) Blockmagnet HF 28/26 B) Ferrimax special anisotropic	0.96
	Turbine / impeller	327-0000/04	Plastic PP	Moplen HP500N coloured with Ampacet 156168 Masterbatch	15.83
	Under housing part	313-45xx	Plastic PBT + 30-35% GF	A) Arnite TV4 270 B) Ultradur B4300 G6 FC Acqua	21.7

Creation: S.Reuge  
 Datum: 05.09.2019

Revision: S.Reuge  
 Datum: 21.03.2022

Approval: S.Schneider  
 Version: 4

Filing: T:\Zulassungs-Zertifikate\Food Contact Compliance\_Weltweit\FHKSC\_2019.08\_Erweiterte weltweite Konformitätserklärung für Lebensmittelkontakt\ARCHIV\DoC Food contact\_FHKSC\_03.2023\_v4.docx



<input checked="" type="checkbox"/> Colouring / Masterbatch	<input checked="" type="checkbox"/> European Union: Regulation 10/2011, Resolution AP (89) 1 on the use of colorants in plastic materials coming into contact with food <input checked="" type="checkbox"/> Finland: Finnish Food Act No. 23/2006 <input checked="" type="checkbox"/> France: French Positive list (Cirulaire No. 176 1959 and its amendments) and French Decree No. 2007-766 <input checked="" type="checkbox"/> Germany: LFGB §30, §31 and BfR Recommendation IX on Colorants for Plastics and other Polymers used in Commodities <input checked="" type="checkbox"/> Italy: Ministerial Decree of 21/3/1973 and its amendments <input checked="" type="checkbox"/> Switzerland: Swiss Food and Commodity Ordinance SR 817.02 <input checked="" type="checkbox"/> USA: FDA Title 21 CFR §177.1520(c)2.1, 3.1a and 21 CFR 178., GRAS <input checked="" type="checkbox"/> China: GB 4806.6-2016 and GB 9685-2016 for food contact materials <input checked="" type="checkbox"/> Japan: Japan Food Sanitation Act, Specifications and Standards for Food, Food Additives, etc. (1959 MHLW Notice No. 370) with Amendments (Positive list of 28 <sup>th</sup> of April 2020) <input checked="" type="checkbox"/> Bisphenol A and Phthalates free	<input checked="" type="checkbox"/>  <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>  <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>  <input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>  <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>  <input checked="" type="checkbox"/>
<input checked="" type="checkbox"/> Ink-jet (on external side of the plastic under part)	<input checked="" type="checkbox"/> EuPIA Guideline on Printing Inks applied to the non-food contact surface of food packaging materials and Articles <input checked="" type="checkbox"/> Switzerland: Annex 10, Swiss Food and Commodity Ordinance SR 817.02, version of 1st of May 2017		<input checked="" type="checkbox"/>  <input checked="" type="checkbox"/>
<input checked="" type="checkbox"/> Silicones	<input checked="" type="checkbox"/> European Union: Resolution ResAP(2004)5 on silicones used for food contact applications <input checked="" type="checkbox"/> Finland: Finnish Food Act No. 23/2006 <input checked="" type="checkbox"/> France: French Decree 2007-766, Order of 25/11/1992 on materials and articles made of silicone elastomers <input checked="" type="checkbox"/> Germany: LFGB §30, §31 and BfR Recommendation XV on silicone <input checked="" type="checkbox"/> Italy: Ministerial Decree of 21/3/1973 and its amendments <input checked="" type="checkbox"/> Netherland: The Dutch Regulation on commodities in contact with food Verpakkingen- en gebruiksartikelenbesluit <input checked="" type="checkbox"/> Switzerland: Ordinance 817.023.21 on commodities with Food contact applications and its amendments and its amendments <input checked="" type="checkbox"/> USA: FDA 21 CFR 177.2600 <input checked="" type="checkbox"/> Mercosur: GMC Res. No.32/10 Technical regulation on migration from plastic material, packaging and equipment intended to come into contact with foods GMC No. 15/10 Technical regulation on Dyes in Plastic Packaging and Equipment used to be in Contact with Food GMC Res. No. 28/99- technical regulation on the positive list for elastomeric materials used in packaging and equipment in contact with food GMC Res. No. 56/92 General provisions for Plastic packaging and food contact equipment GMC Res. No. 3/92 General criteria of packaging and food equipment in contact with foods <input checked="" type="checkbox"/> China: GB 4806.11-2016 National food safety standard - rubber materials and products for food contact use	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>  <input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>  <input checked="" type="checkbox"/>

<input checked="" type="checkbox"/> Silicones (continuation)	<input checked="" type="checkbox"/> Japan: Japan Food Sanitation Act, Specifications and Standards for Food, Food Additives, etc. (1959 MHLW Notice No. 370) <input checked="" type="checkbox"/> Singapore: Sale of Food Act <input checked="" type="checkbox"/> South Korea: Standards & Specifications for Food Utensils, Containers & Packaging <input checked="" type="checkbox"/> Taiwan: Sanitation Standard for Food Utensils, Containers and Packages <input checked="" type="checkbox"/> Bisphenol A and Phthalates free	<input checked="" type="checkbox"/>  <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/> Ceramic / Glass	<input checked="" type="checkbox"/> European Union: Directives 84/500/EEC 84/500 amended by 2005/31/EEC for ceramic articles intended to come into contact with foodstuffs and EDQM "Technical Guide on Metals and alloys used in food contact materials" after Resolution CM/Res(2013) EEC. <input checked="" type="checkbox"/> Finland: Finnish Food Act No. 23/2006 <input checked="" type="checkbox"/> France: French Decree 2007-766 and DGCCRF Document for Food Contact Suitability of Metals and Alloys Intended to Come Into Contact with Foodstuffs <input checked="" type="checkbox"/> Germany: LFGB (Lebensmittel- und Futtermittelgesetzbuch) §30, §31 and its amendments <input checked="" type="checkbox"/> Italy: Ministerial Decree of 21/3/1973 and its amendments <input checked="" type="checkbox"/> Netherland: The Dutch Regulation on commodities in contact with food Verpakkingen- en gebruiksartikelenbesluit, Annex A, Chapter IV <input checked="" type="checkbox"/> Switzerland: Ordinance 817.023.21 and its amendments <input checked="" type="checkbox"/> Mercosur: GMC Res. No. 12/11 on Maximum Inorganic Contaminants in Food GMC Res. No. 46/06 for Metallic Packages and Articles in Contact with Food GMC Res. No. 3/92 General criteria of packaging and food equipment in contact with foods <input checked="" type="checkbox"/> China: GB 4806.4-2016 food safety requirement for ceramic <input checked="" type="checkbox"/> Japan: Japan Food Sanitation Act, Specifications and Standards for Food, Food Additives, etc. <input checked="" type="checkbox"/> Singapore: Sale of Food Act <input checked="" type="checkbox"/> South Korea: Standards & Specifications for Food Utensils, Containers & Packaging - Ministry of Food and Drug Safety <input checked="" type="checkbox"/> Taiwan: Sanitation Standard for Food Utensils, Containers and Packages	<input checked="" type="checkbox"/>  <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>  <input checked="" type="checkbox"/>  <input checked="" type="checkbox"/>  <input checked="" type="checkbox"/>  <input checked="" type="checkbox"/>  <input checked="" type="checkbox"/>  <input checked="" type="checkbox"/>  <input checked="" type="checkbox"/>  <input checked="" type="checkbox"/>  <input checked="" type="checkbox"/>  <input checked="" type="checkbox"/>  <input checked="" type="checkbox"/>  <input checked="" type="checkbox"/>  <input checked="" type="checkbox"/>  <input checked="" type="checkbox"/>  <input checked="" type="checkbox"/>  <input checked="" type="checkbox"/>  <input checked="" type="checkbox"/>  <input checked="" type="checkbox"/>  <input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

The declarant can provide the appropriate documentation in support of the said compliance.  
**Product Certification**



Additionally, our products are classified **NSF/ANSI 169 - Special Purpose Food Equipment and Devices** - according Chapter 4 of the 2000 U.S. FDA Food Code. Please refer to the following link with the official NSF-listing:  
<http://info.nsf.org/Certified/Food/Listings.asp?Company=28180&Standard=169>

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**Particularities**

(EC)Regulation N° 450/2009 on active and intelligent materials and items intended to come into contact with food:

n/a (not applicable)

(EC)Regulation N° 282/2008 on recycled plastic materials and items intended to come into contact with foods:

n/a

**This declaration of compliance has been established in respect of the following:**

Declarations by suppliers of raw materials

Overall Migration testing

Flowmeter part	Simulants	Time	Temperature
Upper & under housing parts	Distilled water (for Arnite)	2 hours	70 °C
	3% Acetic acid and 20% ethanol (for Ultradur)	4 hours	100 °C
Turbine / Impeller	Distilled water	2 hours	70 °C
O-ring	Distilled water	24 hours	40 °C

**Assessment of non-listed substances - Article 6 of (EU) Regulation N° 10/2011**

Not applicable

Risk assessment (article 19 of (EU) Regulation N° 10/2011):

If not, list substances and information relevant to the risk assessment

Nom	Identification CAS - EINECS – N° de Référence MCDA
-	-

**Assessment of non-intentionally added substances (NIAS):**

Not applicable

Risk assessment (article 19 of (EU) Regulation N° 10/2011 and article 11 of Swiss Regulation SR 817.023.21: compliant.

No substances > 0.0028 mg/dm<sup>2</sup> were detected under 3 x 24 h / 40°C with distilled water.

If not, list substances and information relevant to the risk assessment

Nom	Identification CAS - EINECS – N° de Réf. MCDA
-	-

#### 4. Information on substances with restrictions

List of substance(s) subject to restriction and migration limits according to Regulation 10/2011/EC:

FCM No. (10/2011/EC)	CAS No.	Name	Limits (mg/kg)	A*	W*	C*	M*
19	-	N,N-bis(2-hydroxyethyl)alkyl (C 8-C 18)amine	1.2	x			
20	-	N,N-bis(2-hydroxyethyl)alkyl (C 8-C 18)amine hydrochlorides	1.2	x			
246	109-99-9	Tetrahydrofuran	0.6	x			
254	110-63-4	1,4-Butanediol	5.0	x			
433	2082-79-3	Octadecyl 3-(3,5-di-tert-butyl-4- hydroxyphenyl)propionate	6.0	x			
779	182121-12-6	9,9-bis(methoxymethyl)fluorene	0.05	x			
785	0100-21-0	Terephthalic acid	7.5	x			

\* Compliance with these limits was established by Analysis (A), Worst case (W), Calculation (C) or Modelling (M).

In the case of tests, specify the simulant(s) and test conditions:

Flowmeter part	Simulants	Time	Temperature
Upper & under housing parts	Distilled water (for Arnite)	24 hours	40 °C
	3% Acetic acid / 20% ethanol (for Ultradur)	24 hours	70° C
Turbine / Impeller	Distilled water	24 hours	40 °C

If not completed, specify reasons - refer to reference documents:

List of substance(s) subject to restriction but without migration limits according to Regulation 10/2011/EC:

FCM No. (10/2011/ EC)	CAS No.	Name
106	57-11-4	Stearic acid

List of additives having multiple function after Regulation 10/2011/EC (e.g. food additive and packaging additive):

E number	Name of Additive	PM/REF N° and/or CAS N°
E 170	Calcium carbonate	471-34-1
E 470a	Calcium salts of fatty acids	977089-53-4
E 570	Fatty acids (stearic acid)	57-11-4

## 5. Information related to the intended use of the materials or items

Materials or items intended for infants and young children  Yes

No

Type of food intended to be placed in contact:

All types of food products

or

Beverages (such as water)

Alcoholic foods

Acidic foods

Ice creams

Fatty foods:

*If the material and / or item subject to (EU) Regulation N° 10/2011 is concerned by the application of a reduction factor, this should be mentioned:*

Reduction factor due to fat content

Reduction factor related to D2 simulant

Others: .....

### Contact conditions (time and temperatures) corresponding to the input data:

The article and materials thereof covered by this Declaration of Conformity is/are suitable for repeated use in contact with drinking water up to 40 °C for periods of time of 24 consecutive hours each.

**Maximum surface / volume ratio in contact with food used to establish compliance of the material or item (if applicable):** 0.6 dm<sup>2</sup> / 100 ml

**Precaution before use:** please note, that the article has to be rinsed thoroughly with potable water (up to 50°C warm) prior to the first application.

## 6. Functional barrier (FB) in the case of multilayer materials according to Regulation N°10/2011

Not applicable

Or tick the corresponding box if the materials meet the requirements when using a FB:

Multi-layer plastics (Article 13 (2), (3) and (4) of (EU) Regulation N° 10/2011)

Multi-layer materials (Article 14 (2), (3) and (3) of (EU) Regulation N°10/2011)

The material covered by this declaration is to be used only behind a functional barrier

Please note, that this declaration replaces the precedent versions of it.

By observing the above requirements, we have fulfilled our duty of care regarding the compliance of the product we supply.

This declaration is valid on condition that there is no modification of material composition, that its intended use has not changed and in the absence of significant regulatory changes. "The DGGCRF (French Directorate General for Competition, Consumer Affairs and Prevention of Fraud) suggests a maximum duration of 5 years for the validity period of the test reports; if changes that may cause a change in the inertness of the material have occurred during this period, the tests must be repeated." <sup>2</sup>

Compliance is understood to be subject to compliance with the conditions of storage, handling and use, taking into account the specific characteristics of the material or item, and the conditions such as prescribed by professional practices or codes.

**In the event of changes to the nature of the packaged product, its composition or its intended use, as well as in the event of a change in the conditions for using the material or the item, the person for whom this declaration is intended must ensure the compatibility packaging / content for which s/he then accepts responsibility.**

Stefan Schneider

Name

CEO

Position



DIGMESA AG  
Kaltenstrasse 31  
CH 2563 Ipsach

Authorized signature and stamp

Ipsach, 21<sup>th</sup> of March 2022

Place and Date

<sup>2</sup> (ANIA / Food Packaging Platform: Instructions for completing the Declaration of Compliance with food contact legislation, March 2019. <https://www.ania.net/alimentation-sante/declaration-conformite-materiaux-equipements-au-contact-denrees-alimentaires> )