

DECLARATION OF COMPLIANCE WITH FOOD CONTACT LEGISLATION

1. Company Identification

We, Digmesa AG, declare that the article and materials thereof described hereunder 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/xxxx

974-95xx/xxxx

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 (cm2)
	Upper housing part	310-450x	Plastic PBT with 35% glass- fibre (GF)	Arnite TV4 270	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 anisottropic	0.96
	Turbine / impeller	327-0304	Plastic PP	Moplen HP500N coloured with Ampacet 156168 Masterbatch	15.83
	-Under housing part	313-45xx	Plastic PBT + 35% GF	Arnite TV4 270	21.7

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3. Confirmation that those materials or items meet the relevant requirements of Food contact regulations

The materials and/or items covered by this Declaration comply with the relevant requirements laid down in Framework Regulation (EC) N° 1935/2004/EC, Regulation (EC) N°2023/2006 and other European and national texts applicable, listed below:

Relevant categories	List of regulations and / or other references texts applicable	Means of Complia	
of materials		Testing	DoC from Suppliers
☑ Plastics	 ☑ European Union: Regulation No.10/2011/EU on plastic materials and articles and its amendments ☑ France: French Decree No. 2007-766 on materials and articles intended to contact with food and its amendments ☑ Germany: LFGB (Lebensmittel- und 		
	Futtermittelgesetzbuch) §30, §31 and its amendments Italy: Ministerial Decree of 21/3/1973 and its amendments Netherland: The Dutch Regulation on commodities in contact with food "Verpakkingen- en gebruiksartikelenbesluit" (Warenwet)		\boxtimes
	 ☑ USA: (FDA) and its amendments, Title 21 CFR 177.1520-Olefin polymer and 21 CFR 177.1660-Poly (tetramethylene terephthalate) ☑ Mercosur (Argentina, Brazil, Paraguay, Uruguay and Venezuela): 		
	GMC Res. No.32/10 Technical regulation on migration from plastic material, packaging and equipment intended to come into contact with foods 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 ☐ China: GB 4806.7-2016 National food safety standard - plastic materials and articles for food contact use ☐ Japan: Japan Food Sanitation Act, Specifications and Standards for Food, Food Additives, etc. (1959 MHLW Notice No. 370) with Amendments		⊠ 1
	 Singapore: Sale of Food Act South Korea: Standards & Specifications for Food Utensils, Containers & Packaging - Ministry of Food and Drug Safety 		
	☐ Taiwan: Sanitation Standard for Food Utensils, Containers and Packages	\boxtimes	
	☐ Thailand: Food Act B.E. 2522 (1979) and Notification of the Ministry of Public Health (No. 295) B.E. 2548		
	Phthalates and Bisphenol A (BPA) free		

¹ Only for Moplen HP500N (PP used for the turbine)

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N Calaunina	⊠ European Union: Regulation 10/2011, Resolution AP (89) 1	\boxtimes	\boxtimes
Colouring	on the use of colorants in plastic materials coming into contact with food		
Masterbatch	⊠ France: French Positive list (Circulaire No. 176 1959 and its amendments) and French Decree No. 2007-766		\boxtimes
	☐ Germany: LFGB §30, §31 and BfR Recommendation IX on	\boxtimes	\boxtimes
	Colorants for Plastics and other Polymers used in Commodities Italy: Ministerial Decree of 21/3/1973 and its amendments	\boxtimes	
	☑ China: GB 4806.6-2016 and GB 9685-2016 for food contact materials		
	☑ Bisphenol A and Phthalates free	\boxtimes	\boxtimes
Silicones	☑ European Union: Resolution ResAP(2004)5 on silicones used for food contact applications		
		\boxtimes	
	☐ Germany: LFGB §30, §31 and BfR Recommendation XV on silicone	\boxtimes	
	☑ Italy: Ministerial Decree of 21/3/1973 and its amendments		
	Switzerland: Ordinance 817.023.21 on commodities with Food contact applications and its amendments and its		
	amendments ⊠ Netherland: The Dutch Regulation on commodities in	\boxtimes	
	contact with food Verpakkingen- en gebruiksartikelenbesluit	\boxtimes	\boxtimes
	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		
	China: GB 4806.11-2016 National food safety standard -		
	rubber materials and products for food contact use Japan: Japan Food Sanitation Act, Specifications and Standards for Food Food Additives, etc. (1959 MHI W Notice)	\boxtimes	
	Standards for Food, Food Additives, etc. (1959 MHLW Notice No. 370)		
	☑ Singapore: Sale of Food Act☑ South Korea: Standards & Specifications for Food Utensils,		
	Containers & Packaging X Taiwan: Sanitation Standard for Food Utensils, Containers	\boxtimes	
	and Packages ⊠ Bisphenol A and Phthalates free		\boxtimes

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Ceramic / Glass	☑ 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.	
	☑ Italy: Ministerial Decree of 21/3/1973 and its amendments	
	Netherland: The Dutch Regulation on commodities in contact with food "Verpakkingen- en gebruiksartikelenbesluit"	
	☐ GB 4806.4-2016 food safety requirement for ceramic ☐ Switzerland: Ordinance 817.023.21 and its amendments ☐ The Dutch Commodities Act (Regeling Verpakkingen en Gebruiksartikelen (Warenwet)), Annex A, Chapter IV	
	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	
	☑ Singapore: Sale of Food Act☑ South Korea: Standards & Specifications for Food	
	Utensils, Containers & Packaging - Ministry of Food and Drug Safety	
	☐ Taiwan: Sanitation Standard for Food Utensils, Containers and Packages	

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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(EC)Regulation N° 450/2009	on act	tive ar	nd 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	2 hours	70 °C
Turbine / Impeller	Distilled water	2 hours	70 °C
O-ring	Distilled water	24 hours	40 °C

Assessment of non-listed substances	s - Article 6 c	of (EU)	Regulation N°	10/2011
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Not applicable ■	
Risk assessment (article 19	of (EU) Regulation N° 10/2011)
☐ If not, list substances and in	nformation relevant to the risk assessment
Nom	Identification CAS - EINECS - N° de Référence MCDA
-	-

Assessment of non-intentionally a	dded substances	(NIAS):
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☐ Not applicable
\boxtimes Risk assessment (article 19 of (EU) Regulation N° 10/2011): will be done till the end of December 2019
☐ If not, list substances and information relevant to the risk assessment

Nom	Identification CAS - EINECS - N° de Réf. MCDA
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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	х			
20	-	N,N-bis(2-hydroxyethyl)alkyl (C 8-C 18)amine hydrochlorides	1.2	х			
246	109-99-9	Tetrahydrofuran	0.6	Х			
254	110-63-4	1,4-Butanediol	5.0	Х			
433	2082-79-3	Octadecyl 3-(3,5-di-tert-butyl- 4- hydroxyphenyl)propionate	6.0	Х			
779	182121-12- 6	9,9- bis(methoxymethyl)fluorene	0.05	х			
785	0100-21-0	Terepthalic acid	7.5	Х			

^{*} 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	24 hours	40 °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

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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				
☐ Acidic foods ☐ Ice creams				
Fatty foods:				
If the material and / or item subject to (EU) Regulation № 10/2011 is concerned by the application of a reduction factor, this should be mention Reduction factor due to fat content Reduction factor related to D2 simulant	ed:			
Others:				
Contact conditions (time and temperatures) corresponding to the input data:				
The article and materials thereof covered by this Declaration of Conformity is/are so repeated use in contact with drinking water up to 40 °C for periods of time of 24 co hours each.				
Maximum surface / volume ratio in contact with food used to establish comp the material or item (if applicable): 0.6 dm² / 100 ml	liance of			
 6. Functional barrier (FB) in the case of multilayer materials according Regulation N°10/2011 ☑ Not applicable 	to			
Or tick the corresponding box if the materials meet the requirements when using a F	B:			
 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 <u>behind</u> a functional base 	arrier			



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." ²

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

Keltenstrasse 31 CH 2563 Ipsach

Ipsach, 02nd of September 2019

Authorized signature and stamp

Place and Date

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² (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)