

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

(with x for digit from 1 to 9)

974-95xx-Axxx, 974-95xx-Bxxx, 974-96xx-Axxx

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	310-450x	Plastic PBT	A) Arnite TV4 270	18.9
	housing part		with 30-35% glass-fibre (GF)	B) Ultradur B4300 G6 FC Acqua	
	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	0.96
				B) Ferrimax special anisottropic	
	Turbine /	327-	Plastic	Moplen HP500N	15.83
	impeller	0000/04	PP	coloured with Ampacet 156168 Masterbatch	
	Under	313-45xx	Plastic PBT	A) Arnite TV4 270	21.7
	housing part		+ 30-35% GF	B) Ultradur B4300 G6 FC Acqua	

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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 o	
of materials		Testing	DoC from Suppliers
⊠ Plastics	☑ European Union: Regulation No.10/2011/EU on plastic materials and articles and its amendments, including 15 th amendment No. 2020/1245/EU		
	 ⊠ Finland: Finnish Food Act No. 23/2006 ⊠ 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	\boxtimes	
	 ☑ Italy: Ministerial Decree of 21/3/1973 and its amendments ☑ Netherland: The Dutch Regulation on commodities in contact with food "Verpakkingen- en gebruiksartikelenbesluit" (Warenwet) 		
	 (Warenwet) Switzerland: Swiss Food and Commodity Ordinance SR 817.02 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):	\boxtimes	\boxtimes
	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	 ⊠¹	∑ 2
	☐ China: GB 4806.7-2023 National food safety standard - plastic materials and articles for food contact use		
	 ☑ Singapore: Sale of Food Act ☑ South Korea: Standards & Specifications for Food Utensils, Containers & Packaging - Ministry of Food and Drug Safety 	\boxtimes	
	☐ 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	\boxtimes	\boxtimes

¹ Ultradur B4300 G6 FC Acqua was tested after China GB 4806:2016

² Only for Moplen HP500N (PP used for the turbine)

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☐ Colouring / Masterbatch	⊠ European Union: Regulation 10/2011, Resolution AP (89) 1 on the use of colorants in plastic materials coming into contact		
	with food ⊠ Finland: Finnish Food Act No. 23/2006 ⊠ France: French Positive list (Circulaire No. 176 1959 and	\boxtimes	
	its amendments) and French Decree No. 2007-766 ☑ Germany: LFGB §30, §31 and BfR Recommendation IX on Colorants for Plastics and other Polymers used in Commodities	\boxtimes	\boxtimes
	 Italy: Ministerial Decree of 21/3/1973 and its amendments Switzerland: Swiss Food and Commodity Ordinance SR 817.02 USA: FDA Title 21 CFR §177.1520(c)2.1, 3.1a and 21 CFR 178., GRAS 	\boxtimes	
	☑ China: GB 4806.7-2023 and GB 9685-2016 for food contact materials		
	☑ Japan: Japan Food Sanitation Act, Specifications and Standards for Food, Food Additives, etc. (1959 MHLW Notice No. 370) with Amendments (Positive list of 28 th of April 2020)	\boxtimes	
	⊠ Bisphenol A and Phthalates free	\boxtimes	\boxtimes
☐ Ink-jet (on external side of the plastic	 ⊠ EuPIA Guideline on Printing Inks applied to the non-food contact surface of food packaging materials and Articles 		
under part)	☐ Switzerland: Annex 10, Swiss Food and Commodity Ordinance SR 817.02, version of 1st of May 2017		
	☑ European Union: Resolution ResAP(2004)5 on silicones used for food contact applications		\boxtimes
	⊠ Finland: Finnish Food Act No. 23/2006	\boxtimes	
	☐ Germany: LFGB §30, §31 and BfR Recommendation XV on silicone		
	Italy: Ministerial Decree of 21/3/1973 and its amendments Netherland: The Dutch Regulation on commodities in contact with food Verpakkingen- en gebruiksartikelenbesluit		
	Switzerland: Ordinance 817.023.21 on commodities with Food contact applications and its amendments and its amendments		
	□ USA: FDA 21 CFR 177.2600 □ Mercosur: □ Merc		
	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		

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Silicones (continuation)			
	⊠ Singapore: Sale of Food Act		
_	South Korea: Standards & Specifications for Food Utensils,	\boxtimes	
	Containers & Packaging		
	☐ Taiwan: Sanitation Standard for Food Utensils, Containers		
	and Packages	\boxtimes	
<u> </u>	⊠ Bisphenol A and Phthalates free		
⊠ Ceramic /	European Union: Directives 84/500/EEC 84/500	\boxtimes	
Glass	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.		
	☐ Finland: Finnish Food Act No. 23/2006		
	☐ France: French Decree 2007-766 and DGCCRF		
	Document for Food Contact Suitability of Metals and Alloys		
	Intended to Come Into Contact with Foodstuffs		
	☐ Germany: LFGB (Lebensmittel- und	\boxtimes	
	Futtermittelgesetzbuch) §30, §31 and its amendments		
		\boxtimes	
	amendments		
	Netherland: The Dutch Regulation on commodities in		
	contact with food Verpakkingen- en gebruiksartikelenbesluit, Annex A, Chapter IV		
	Switzerland: Ordinance 817.023.21 and its amendments	5	
	✓ Mercosur:		
		\boxtimes	
	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		
	☐ China: GB 4806.9-2023 food safety requirement for		
	metals		
	☐ Japan: Japan Food Sanitation Act, Specifications and		
	Standards for Food, Food Additives, etc.	_	
	☑ 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,	\boxtimes	
	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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Particularities

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

(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

Flowmeter part	Simulants	Time	Temperature
Upper & under housing	Distilled water (for Arnite)	2 hours	70 °C
parts	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° 1	10/2011
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⊠ Not applicable	, ,
☐ Risk assessment (article 19 of (EU	J) Regulation N° 10/2011):
☐ If not, list substances and informa	tion 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 2 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
-1	=

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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	E	N,N-bis(2-hydroxyethyl)alkyl (C 8-C 18)amine	1.2	х			
20	12	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	Distilled water (for Arnite)	24 hours	40 °C
parts	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

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5.	Information related to the intended use of the materials or items		
Ma	terials or items intended for infants and young children ☐ Yes		
Ту	pe of food intended to be placed in contact:		
	All types of food products		
or			
\boxtimes	Beverages (such as water)		
	Acidic foods		
	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 mentioned: ☐ Reduction factor due to fat content ☐ Reduction factor related to D2 simulant		
	Others:		
	ontact conditions (time and temperatures) corresponding to the input data:		
rep	e article and materials thereof covered by this Declaration of Conformity is/are suitable for beated use in contact with drinking water up to 40 °C for periods of time of 24 consecutive urs each.		
Ma the	aximum surface / volume ratio in contact with food used to establish compliance o e material or item (if applicable): 0.6 dm² / 100 ml		
Pr Wa	ecaution before use: please note, that the article has to be rinsed thoroughly with potable ater (up to 50°C warm) prior to the first application.		
	Functional barrier (FB) in the case of multilayer materials according to Regulation N°10/2011 Not applicable		
Or 	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		

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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." 3

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	CEO
Name	Position
DIGNESA AG Keltenatrasse 31 GH/2563 Ipsach	lpsach, 16 th of December 2024
Authorized signature and stamp	Place and Date

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³ (ANIA / Food Packaging Platform: Instructions for completing the Declaration of Compliance with food contact legislation, March 2019. https://www.ania.net/alimentation-sante/declaration-conformitemateriaux-equipements-au-contact-denrees-alimentaires)