

DECLARATION OF COMPLIANCE WITH FOOD CONTACT LEGISLATION

1. Company Identification

We, Digma 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 Nano DM60

Item numbers: 93N-6211-1100x with x for digit from 0 to 9

Description: The nano DM60 Flow Sensor is a general-purpose device that has been specially designed for coffee machines that use vibratory pumps. The device is installed between the water tank and the vibration pump (on the suction side). This way measuring errors that arise during pulsating water flow caused by vibration pumps are minimized.

Picture of the article:



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

Product build-up				
Part designation	Measuring tube	Turbine / Impeller	Magnets	Impeller cage
Part number	309-0002/01	A) 527-0002/01EX B) 527-0K02/01EX	480-0007	370-0001/01
Material type	Plastic PP	Plastic PVDF	Ceramic Hard ferrite	Plastic PP
Material formulation	Borcom WGA1140	A) Solef 1008-0001 B) Kynar 720 / 720E	Blockmagnet HF 28/26	Moplen HP500N
Max. food contact area (cm²)	4.938	0.332	0.055	0.504

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
Measuring tube	Distilled water	2 hours	70 °C
Turbine / Impeller	Distilled water	2 hours	70 °C
Impeller cage	Distilled water	2 hours	70 °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): No migrants detected beyond risky proportions with food simulant C (20% ethanol) under 3 x 24 h / 65°C.

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

Nom	Identification CAS - EINECS – N° de Réf. MCDA
Peroxides	Regulated Aid to Polymerization after Resolution AP (92)2 from Council of Europe: (SMLT: 0.05 mg/kg (as active oxygen when extracted into distilled water).

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		x	
20	-	N,N-bis(2-hydroxyethyl)alkyl (C 8-C 18)amine hydrochlorides	1.2	x		x	
132	75-38-7	Vinylidene fluoride	5.0	x			
368	693-36-7	Thiodipropionic acid, dioctadecyl ester	5.0	x			
433	2082-79-3	Octadecyl 3-(3,5-di-tert-butyl-4- hydroxyphenyl)propionate	6.0	x		x	
779	182121-12-6	9,9-bis(methoxymethyl)fluorene	0.05	x		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
Measuring tube	Distilled water	24 hours	40 °C
Turbine / Impeller	Distilled water (Solef)	24 hours	40 °C
	In-house laboratory method not disclosed (Kynar)	unknown	unknown
Impeller cage	Distilled water	24 hours	40 °C

Note: the material of the impeller cage (Moplen HP500N) was tested on another item and each regulated substance was in conformity with the Specific Migration Limits. The food contact ratio of the tested object being much higher than the one the impeller cage, the results can be taken into consideration, moreover with a safety margin for the nano configuration.

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

Not applicable

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 470a	Calcium salts of fatty acids	977089-53-4
E 553b	Talc	14807-96-6

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

 Beverage / aqueous foods (such as water) Fatty foods: Alcoholic foods Acidic foods Ice creams

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 the above-mentioned type of food 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 dm² / 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." ¹

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


DIGMESA AG
Keltenstrasse 31
CH 2563 Ipsach

Ipsach, 16th of October 2024

Authorized signature and stamp

Place and Date

¹ (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>)