

**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**

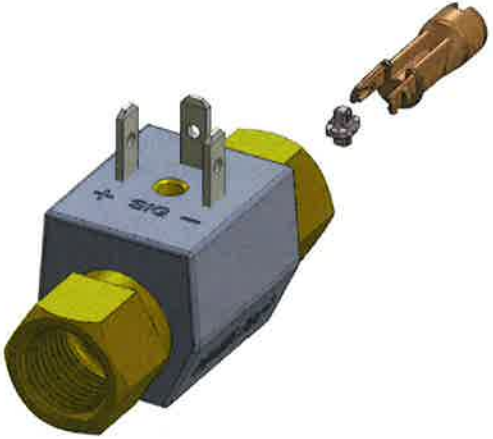
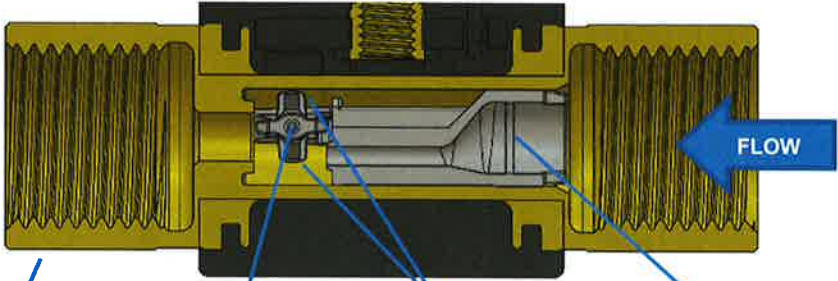
**Commercial name:** Flowmeter Nano Brass

**Item numbers:** 9NB-xxxx/xxx with x for digits from 1 to 9

**Description:** The Flow Sensor nano is a general-purpose device. It is employed for measuring, regulating or metering and guarantees most precise measurement of fluid quantities. In addition, a pulse generator integrated into the flowmeter guarantees a practically unlimited useful life.

**Picture of the article:**

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

<p><b>Product build-up</b></p>				
<p><b>Product profile cut</b></p>				
<p><b>Part designation</b></p>	<p>Measuring tube</p>	<p>Turbine / Impeller</p>	<p>Magnets</p>	<p>Impeller cage</p>
<p><b>Part number</b></p>	<p>404-2600/0x</p>	<p>527-0002/0xEX</p>	<p>480-0007</p>	<p>370-0002/01x0</p>
<p><b>Material type</b></p>	<p>Low-lead brass alloy</p>	<p>Plastic PVDF</p>	<p>Ceramic Hard ferrite</p>	<p>Plastic PEEK</p>
<p><b>Material formulation</b></p>	<p>EcoBrass CW724R (CuZn21Si3P)</p>	<p>Solef 1008-0001 unreinforced</p>	<p>Blockmagnet HF 28/26</p>	<p>Victrex PEEK 450G unreinforced</p>
<p><b>Max. food contact area (cm<sup>2</sup>)</b></p>	<p>4.73</p>	<p>0.332</p>	<p>0.055</p>	<p>3.67</p>

### 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 of materials	List of regulations and / or other references texts applicable	Means of Compliance	
		Testing	DoC from Suppliers
<input checked="" type="checkbox"/> Plastics	<input checked="" type="checkbox"/> European Union: Regulation No.10/2011/EU on plastic materials and articles and its amendments <input checked="" type="checkbox"/> France: French Decree No. 2007-766 on materials and articles intended to contact with food and its amendments <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" (Warenwet) <input checked="" type="checkbox"/> USA: (FDA) and its amendments, Title 21 CFR 177.2510 - Polyvinylidene fluoride resins.and 21 CFR 177.2415 - Poly(aryletherketone) resins <input checked="" type="checkbox"/> 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 <input checked="" type="checkbox"/> China: GB 4806.7-2016 National food safety standard - plastic materials and articles for food contact use <input checked="" type="checkbox"/> Japan: Japan Food Sanitation Act, Specifications and Standards for Food, Food Additives, etc. (1959 MHLW Notice No. 370) with Amendments <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"/> Thailand: Food Act B.E. 2522 (1979) and Notification of the Ministry of Public Health (No. 295) B.E. 2548 <input checked="" type="checkbox"/> Phthalates and Bisphenol A (BPA) free	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <sup>1</sup> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <sup>1</sup> <input checked="" type="checkbox"/> <sup>1</sup> <input checked="" type="checkbox"/> <sup>1</sup> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <sup>1</sup> <input checked="" type="checkbox"/> <sup>1</sup> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <sup>1</sup> <input checked="" type="checkbox"/> <sup>1</sup> <input checked="" type="checkbox"/> <sup>1</sup> <input checked="" type="checkbox"/> <sup>1</sup> <input checked="" type="checkbox"/> <sup>1</sup> <input checked="" type="checkbox"/> <sup>1</sup> <input checked="" type="checkbox"/> <sup>1</sup> <input checked="" type="checkbox"/> <sup>1</sup> <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"/> Metal / Brass alloy	Lead content < 0.09 % (w/w)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

<sup>1</sup> Only valid for PVDF Solef



**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
Impeller cage	Distilled water, 3% acetic acid and sunflower oil	24 hours	40 ° C
Turbine / Impeller	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): only performed for PVDF Solef.

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*
132	75-38-7	Vinylidene fluoride	5.0	x			
201	102-09-0	Diphenyl carbonate	0.05	x			
295	123-31-9	1,4-dihydroxybenzene	0.6	x		x	
313	127-63-9	diphenyl sulphone	3.0	x		x	
337	345-92-6	4,4'-difluorobenzophenone	0.05	x		x	

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

Migration tests were performed on another part than the one mentioned in this document but with identical plastics type and formulation. Calculations showed that the weight / food contact surface ratio of the present mentioned plastic part is comparable to the samples tested and therefore acceptable to guarantee the compliance.

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

Flowmeter part	Simulants	Time	Temperature
Impeller cage	Distilled water, ethanol and oil	24 hours	40 °C
Turbine / Impeller	Distilled water	24 hours	40 °C

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

Migration testing of not disclosed substances with restrictions in Victrex will be ordered in the third quarter of 2020.

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
n/a	-	none

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

E number	Name of Additive	Generic FCM No. (10/2011/EC)
E339	Sodium phosphates	509

**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 100 °C (hot-filling) for up to 15 minutes or 30°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 warm potable water 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

CEO

Name

Position

  
DIGMESA AG  
Keltenstrasse 31  
CH 2563 Ipsach

Ipsach, 08<sup>th</sup> of February 2022

Authorized signature and stamp

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> )