

# Konformitätserklärung Declaration of Compliance

**Company** Endress+Hauser Flowtec AG, Kägenstrasse 7, 4153 Reinach BL1, Switzerland

being the manufacturer, declares that the following materials used in

**Product** Promag H and Dosimag

Promag 10/50/53/55 H, Dosimag

Material Group	Material	Product contact part	Applicable to order code options
Plastic	PFA	Liner	All
Metal	1.4435/316L	Electrodes	Feature 030: Options: 0, G
Metal	Alloy C-22	Electrodes	Feature 030: Options: 1
Metal	1.4404/316L	Process Connections	Feature 010: Options: U,V,W,Q,T,0,1,2,3,4,5,6,8
Elastomer	VMQ (Silicone)	Gasket	Feature 020*: Option: H

Promag H 10/100/300/500

Material Group	Material	Product contact part	Applicable to order code options
Plastic	PFA	Liner	All
Metal	1.4435/316L	Electrodes	Feature 075: Options: 0, G
Metal	Alloy C-22	Electrodes	Feature 075: Options: 1
Metal	1.4404/316L	Process Connections	Feature 070: Options: AAS, DAS, DBS, DCS, DDS, DES, FAS, IAS, IBS, ICS, SAS
Elastomer	VMQ (Silicone)	Gasket	Feature 060*: Option: H

are in conformity with following Chinese Regulations where applicable:

**Regulations** Products comply with GB 4806.1-2016 "National Food Safety Standard: General Safety Requirements for Food Contact Materials and Products", GB 9685-2016 "National Food Safety Standard: Standard for Uses of Additives in Food Contact Materials and Articles" and GB 4806.9 National Food Safety Standard: Food Contact Metal Materials and Products ", and GB 4806.7 National Food Safety Standard: Food Contact Plastic Materials and Products for the relevant requirements of this product, and GB 4806.11 National Food Safety Standard: Food Contact Rubber Materials and Products for above mentioned material option.

\* For further gasket options applicable to order code options below please refer to Annex II:  
Promag 10/50/53/55H, Dosimag; Feature 020  
Promag H 10/100/300/500; Feature 060

Conditions For use in accordance with product specifications.

Specifications for intended use or limitations:

The material is suitable for the use in applications with the following types of food:

All kinds of food (Aqueous, acidic, alcoholic, lacteal, fatty and oily food)

Duration and temperature of treatment and storage for contact with food:

Repeated use:  $T_M = 150\text{ }^{\circ}\text{C}$

Relation of surface in contact with food and volume, the conformity of the material or articles is based upon:

For each component different. Consideration of whole product range.

Simulants and test conditions: see Annex for details.

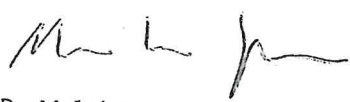
The PFA resin used in the above named devices fulfill the specification given in GB 4806.6 Appendix A for the category PFA:

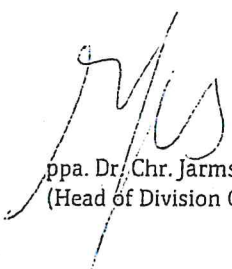
Tetrafluoroethylene: SML/QM = 0,05 mg/kg

Traceability of product in accordance with Regulation GB 31603-2015 is assured by means of serial number on sensor.

This is to emphasize that the customer is obliged to verify the suitability of our products with regard to the intended application. This declaration of conformity is only valid for standard products in their delivery status produced before December 31st, 2024

Reinach, 01.10.2022  
Endress+Hauser Flowtec AG

  
Dr. M. Lehmann  
(Geschäftsführer/Managing Director)

  
ppa. Dr. Chr. Jarms  
(Head of Division QM)

**Annex I:**

Physicochemical index - PFA

Test	Limit	Assessment	Test requirement source	Methods and conditions for verifying compliance
Overall migration, mg/dm <sup>2</sup>				
4%(v/v) acetic acid, 100°C, 4h	≤10	Pass	GB 4806.7-2016	Test method GB 31604.8-2016
10%(v/v) ethanol, reflux temperature, 4h	≤10	Pass		
95%(v/v) ethanol 60°C, 3h	≤10	Pass		
Isooctane, 60°C, 4d	≤10	Pass		
Quantity of KMnO <sub>4</sub> consumed, mg/kg				
Distilled water, 60°C, 2h	≤10	Pass	GB 4806.7-2016	Test method GB 31604.2-2016
Heavy metal (as Pb), mg/kg				
4% (v/v) acetic acid, 60°C, 2h	≤1	Pass	GB 4806.7-2016	Test method GB 31604.9-2016
Decolor test				
Scrubbed by vegetable oil	Negative	Pass	GB 4806.7-2016	Test method GB 31604.7-2016
Scrubbed by ethanol	Negative	Pass		
Immersed solution	Negative	Pass		

Physicochemical index - 1.4435/316L; 1.4404/316L

Test	Limit mg/kg	Assessment	Test requirement source	Methods and conditions for verifying compliance
<b>Migration of heavy metals</b>			GB 4806.9-2016	Test method GB 31604.49-2016 4% (v/v) acetic acid boiled for 30 min, then room temperature for 24h.
Arsenic (As)	≤0.04	Pass		
Cadmium (Cd)	≤0.02	Pass		
Lead (Pb)	≤0.05	Pass		
Chromium (Cr)	≤2.0	Pass		
Nickel (Ni)	≤0.5	Pass		

Physicochemical index – Alloy C-22

Test	Limit mg/kg	Assessment	Test requirement source	Methods and conditions for verifying compliance
Migration of heavy metals				
Arsenic (As)	≤0.04	Pass	GB 4806.9-2016	Test method GB 31604.49-2016 2 <sup>nd</sup> part, 2 <sup>nd</sup> method
Cadmium (Cd)	≤0.02	Pass		5g/L citric acid boiling temperature, 2h
Lead (Pb)	≤0.2	Pass		
Migration of heavy metals				
Arsenic (As)	≤0.04	Pass	GB 4806.9-2016	Test method GB 31604.49-2016 2 <sup>nd</sup> part, 2 <sup>nd</sup> method
Cadmium (Cd)	≤0.02	Pass		Artificial tap water, boiling temperature, 2h
Lead (Pb)	≤0.2	Pass		

Physicochemical index - VMQ (silicone)

Test	Limit mg/kg	Assessment	Test requirement source	Methods and conditions for verifying compliance
Overall migration, mg/dm2				
4% (v/v) acetic acid, reflux, 4h	≤10	Pass	GB 4806.11- 2016	Test method GB 31604.8-2016
10% (v/v) ethanol, reflux, 4h	≤10	Pass		
50% (v/v) ethanol reflux, 4h	≤10	Pass		
Quantity of KMnO4 consumed, mg/kg				
Distilled water, 60°C, 0.5h	≤10	Pass	GB 4806.11- 2016	Test method GB 31604.2-2016
Heavy metal (as Pb), mg/kg				
4% (v/v) acetic acid, 60°C, 0.5h	≤1	Pass	GB 4806.11- 2016	Test method GB 31604.9-2016

## Annex II:

### Gaskets

Gaskets supplied with the product are supplied by 3<sup>rd</sup> party.

In lack of a Declaration of Compliance from supplier, Endress+Hauser Flowtec AG had carried out migration tests for these parts according to following conditions.

### Material: EPDM

Promag 10/50/53/55H, Dosimag; Feature: 020; Option: F

Promag H 10/100/300/500; Feature: 060; Option: F

### Physicochemical index

Test	Limit mg/kg	Assessment	Test requirement source	Methods and conditions for verifying compliance
Overall migration, mg/dm2				
4% (v/v) acetic acid, reflux, 4h	≤10	Pass	GB 4806.11- 2016	Test method GB 31604.8-2016
10% (v/v) ethanol, reflux, 4h	≤10	Pass		
50% (v/v) ethanol reflux, 4h	≤10	Pass		
Quantity of KMnO4 consumed, mg/kg				
Distilled water, 60°C, 0.5h	≤10	Pass	GB 4806.11- 2016	Test method GB 31604.2-2016
Heavy metal (as Pb), mg/kg				
4% (v/v) acetic acid, 60°C, 0.5h	≤1	Pass	GB 4806.11- 2016	Test method GB 31604.9-2016



**FKM, Viton**

Promag 10/50/53/55H, Dosimag; Feature: 020; Option:G

Promag H 10/100/300/500; Feature: 060; Option: G

**Physicochemical index**

Test	Limit mg/kg	Assessment	Test requirement source	Methods and conditions for verifying compliance
Overall migration, mg/dm2				
4% (v/v) acetic acid, 70°C, 0.5h	≤10	Pass	GB 4806.11- 2016	Test method GB 31604.8-2016
10% (v/v) ethanol, reflux, 4h	≤10	Pass		
50% (v/v) ethanol reflux, 4h	≤10	Pass		
Quantity of KMnO4 consumed, mg/kg				
Distilled water, 60°C, 0.5h	≤10	Pass	GB 4806.11- 2016	Test method GB 31604.2-2016
Heavy metal (as Pb), mg/kg				
4% (v/v) acetic acid, 60°C, 0.5h	≤1	Pass	GB 4806.11- 2016	Test method GB 31604.9-2016