Declaration of Compliance



Company Endress+Hauser SE+Co. KG, Hauptstrasse 1, 79689 Maulburg

being the manufacturer, declares that the "process-wetted parts" of the products

Product Micropilot

FMR20B and FMR30B

Material group	Material	Order codes	Process-wetted parts
Plastics	PVDF ¹⁾	070 **	Antenna,
		110 ***	Process Connection Antenna End
Rubber	EPDM ²⁾	070: BM	Gasket

are in conformity with following European Regulations:

Regulations

Regulation (EC) No. 1935/2004, on materials and articles intended to come into contact with food. Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.

1) PVDF

Regulation (EU) 10/2011 on plastic materials and articles intended to come into contact with food.

• Overall Migration Test:

Test conditions:

Simulant	Temperature	Time
10 % ethanol	60 ℃	10 days
95% ethanol	60 ℃	10 days
Iso-octane	20° C	10 days
Iso-octane	60° C	4 h
4 % acetic acid	60 °C	10 days

Test Results:

Simulant	Limit	Result
10 % ethanol	10 mg/dm ²	passed
	60 mg/kg food	passed
95 % ethanol	10 mg/dm ²	passed
	60 mg/kg food	passed
Iso-octane 20°C / 10 d	10 mg/dm ²	passed
	60 mg/kg food	passed

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Iso-octane 60°C / 4 h	10 mg/dm²	passed
	60 mg/kg food	passed
4 % acetic acid	10 mg/dm ²	passed
	60 mg/kg food	passed

• Specific Migration Test:

Test conditions:

Simulant	Temperature	Time
95 % ethanol	60 °C	10 d

Test Results:

Three substances with restrictions set out in Annex I (Regulation (EU) 10/2011) are used in production of this polymer. The SML (Specific Migration Limits) for the substances are set to 1 mg/kg respective 5 mg/kg food and the substances were not detectable in the analysis. The identity of these substances was only disclosed for testing purposes under a signed non-disclosure agreement to the laboratory commissioned to perform the analysis.

• Sensory Tests

The polymer material may influence the taste of the food material. It is recommended that the operator performs sensory tests with the applicable food or food simulant.

• Non-intentionally added substances (NIAS):

To the best of our knowledge, no NIAS are present in the product. Furthermore, our evaluation shows no production processes that add or yield not regulated substances or NIAS in a relevant and/or harmful amount. However, we cannot rule out the presence of NIAS in principle.

- According to the raw material manufacturer, no dual-use additives according to regulation (EC) No 1333/2008 and (EC) No 1334/2008 are used during polymerization or in any step of production.
- Functional barrier:

The material is not a multilayer material and therefore does not contain a functional barrier.

2) **EPDM**:

The EPDM material complies with the German BfR (*Bundesinstitut für Risikobewertung* / federal agency for risk assessment) recommendations XXI Category 4 and the French regulation *Arrêté français du 5 Aout 2020*. (Regulation from August 5, 2020 relating to rubber materials and objects intended to come into contact with foodstuffs and pacifiers for infants and young children) The material is suitable for all aqueous, acidic and alcoholic foods as well as dairy products.

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Additional information:

The products must be cleaned before use, as appropriate for the application. This declaration of conformity emphasizes that the customer is obliged to test the product regarding its suitability in the application. This declaration of conformity is exclusively valid for the listed products as supplied to customer and without any further modification. Since the conditions of use are beyond Endress+Hauser's control, Endress+Hauser makes no warranties, expressed or implied, and assumes no liability in connection with any use of this declaration.

This declaration of compliance refers to the compliance of the mentioned materials with the listed regulations. No further suitability of the products for a specific purpose shall be derived from this.

Maulburg, 2025-01-21	
Endress+Hauser SE+Co. KG	
i.V. Simon Greth	i.V. Stefan Jäger
Dept. Manager R&D Devices Level Continuous	Dept. Manager R&D Qualitymanagement/FSN

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