



## DECLARATION OF COMPLIANCE

according to Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, Annex IV

### The identity and address of the business operator issuing the declaration of compliance:

Trade name: COMAC CAL s.r.o.  
Address: Třanovice 239, 739 53, Czech Republic  
Company registration number: 61974170  
VAT number: CZ61974170

### The identity and address of the manufacturer:

Trade name: COMAC CAL s.r.o.  
Address: Třanovice 239, 739 53, Czech Republic  
Company registration number: 61974170  
VAT number: CZ61974170

### The identity of the product:

Product description: **Electromagnetic flowmeter FLOW 33 and FLOW 38** is intended to measure flow of liquid foodstuffs. Both of the models consist of the same components and differ each from other only in the evaluate unit.  
The product is intended for repeated use.

Electromagnetic flowmeters FLOW 33 and FLOW 38 meet the relevant requirements laid down in Article 3, 11(5), 15 and 17 of Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food, in force.

Plastic parts of flowmeters intended to come to the direct contact with food meet the relevant requirements laid down in Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, in force and in Czech Ministry of Health Decree No. 38/2001 Coll., on hygienic requirements for the articles intended to come into contact with foodstuffs, in force.

Stainless steel parts of flowmeters intended to come to the direct contact with food meet the relevant requirements laid down in Czech Ministry of Health Decree No. 38/2001 Coll., on hygienic requirements for the articles intended to come into contact with foodstuffs, in force and in Council of Europe Resolution CM/Res(2013)9 on metals and alloys used in food contact materials and articles.

Rubber parts of flowmeters intended to come to the direct contact with food meet the relevant requirements laid down in Czech Ministry of Health Decree No. 38/2001 Coll., on hygienic requirements for the articles intended to come into contact with foodstuffs, in force.

### Substances that are subject to restrictions according to Annex I and II to Regulation 10/2011 (plastic parts):

The above mentioned product (plastic parts intended to come to the contact with foods) contains the substances restricted with the specific migration limits (hereinafter SML) according to the Annex I:

- Perfluoropropyl(perfluorovinyl)ether, CAS No 1623-05-8, FCM 423, SML= 0,05 mg/kg or mg/6 dm<sup>2</sup>;
- Tetrafluoroethylene, CAS No 116-14-3, FCM 281, SML= 0,05 mg/kg or mg/6 dm<sup>2</sup>.



The compliance with SML for the above mentioned substances was demonstrated by the determination of residual contents in the plastic part mass and recalculation for the contents of these substances in 6 dm<sup>2</sup>. The compliance was demonstrated for all food types.

The parts intended to come to the direct contact with food do not contain intentionally added primary aromatic amines and the elements listed in Annex II. Compliance with the specific migration limits binding for the elements and primary aromatic amines in the range of Commission Regulation (EU) 2020/1945 amending Commission Regulation (EU) 10/2011, was verified experimentally at migration conditions for the repeated use at the temperature 100°C for the period 5 minutes.

**Specification of the product use (in respect to the plastic part):**

Food types: All of the food types for which the flow is measurable by the given flowmeter. Food simulants A, B and substitute fatty food simulants were used for the compliance demonstration.

Maximal contact period / temperature: Short-time repeated contact at the temperatures up till 100°C for the period up till 5 minutes.

To demonstrate the compliance the following conditions were used: for overall migration - OM2 conditions = 70°C/2 h; for specific migration 100°C/5 minutes.

Contact ratio: The compliance was verified for the contact ratio 6 dm<sup>2</sup>/ 1 kg food.

The plastic parts do not contain a functional barrier.

**For the given use of the product all of the migration limits and the other restrictions are observed. The product does not deteriorate organoleptic properties of foods.**

**Declaration:**

The company **COMAC CAL s.r.o.** hereby declares, that the product „**Electromagnetic flowmeter FLOW 33 and FLOW 38**“ is in compliance with the requirements of:

- **Czech Ministry of Health Decree No. 38/2001 Coll.**, on hygienic requirements for the articles intended to come into contact with foodstuffs, in force.
- **Commission Regulation (EU) No 10/2011** on plastic materials and articles intended to come into contact with food, in force.
- **Regulation (EC) No 1935/2004 of the European Parliament and of the Council** on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, in force.
- **Law No 258/2000 of Czech Republic legal code** on protection of public health, in force.

The product is manufactured **in accordance with the rules for good manufacturing practice according to Commission Regulation (EU) 2023/2006.**

Issued in Třanovice on: 2. 10. 2023, Czech Republic



**COMAC CAL s.r.o.**  
Třanovice 239 -10-  
DIČ: CZ61974170  
provozní středisko  
Těšínská 737/30, 735 42, Těrticko

Signature, stamp:

[WWW.COMACCAL.COM](http://WWW.COMACCAL.COM)