



INSTITUT PRO TESTOVÁNÍ A CERTIFIKACI, a. s.
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic
TESTING LABORATORY - TESTING DIVISION

issues

ATTEST
No. 472111404

On samples:

High-frequency level sensor RFLS-35N-2-CI
materials: PTFE and stainless steel

Client:

DINEL, s.r.o.

U Tescomy 249, 760 01 Zlín, Czech Republic; ID: 634 76 886

Evaluation of the measured parameters:

The evaluated parameters mentioned on the pages 3 – 6 of the Attest **meet** hygienic requirements for the **products made of plastics and stainless steel** given by **Czech Health Ministry Decree No. 38/2001 Coll.**, relating to hygienic requirements for the articles intended to come into contact with foodstuffs, as amended and by **Commission Regulation (EU) No. 10/2011 of 14th January 2011** on plastic materials and articles intended to come into contact with food, as amended.

Food contact conditions:

- Contact with all foodstuff types at temperatures up to 100 °C for up to 2 hours
 - Ratio: 1 piece of the sensor/1000 g (ml) of food (or more)
- The evaluated sample of PTFE material meets requirements for the substances limited by their specific migration limits (SML):

- According to the Annex I of Commission Regulation 10/2011: No low-molecular substances restricted by SML were identified by TD-GC-MS method in PTFE material.
- According to the Annex II of Commission Regulation 10/2011: metals (Al, Ba, Co, Cu, Fe, Li, Mn, Ni, Zn) and primary aromatic amines.

The evaluated sample of stainless steel meets the limits for migration of the selected metallic elements into 0.5% citric acid according to „A practical guide for manufacturers and regulators: Metals and alloys used in food contact materials and articles“, issued by European Directorate for the Quality of medicines & HealthCare.

The evaluated sample does not cause a deterioration in the organoleptic characteristics of food.

The evaluated sample meets requirements of the article 3 of **Regulation (EC) No. 1935/2004 of the European Parliament and of the Council** on materials and articles intended to come into contact with food.

Assessment of raw materials as required under the article 5 and the Annex I to Commission Regulation 10/2011 is not a part of this attest.

This Attest was issued on the basis of the accredited test reports Ref. No. 472111404-01 issued on September 5, 2018.

Issued on: September 5, 2018

Valid till: September 30, 2021



Ing. Jiří Samsonek, Ph.D.
Head of the testing laboratory

Conditions for use of the Attest and associated information:

1. The Attest applies only to the sample tested by our laboratory.
2. The Attest remains in effect until production technology, initial materials and standards or corresponding regulations are changed; however, its validity will extend beyond the period of its effect.
3. If further requirements of national or EU legal regulations apply to the product, the Attest does not replace procedures and documents necessary for assessment of compliance with these regulations.



ATTEST
No. 472111404



Fig. No. 1: High-frequency level sensor RFLS-35N-2-CI

Submitted samples:



Fig. No. 2: PTFE material



Fig. No. 3: Stainless steel



Conditions for use of the Attest and associated information:

1. The Attest applies only to the sample tested by our laboratory.
2. The Attest remains in effect until production technology, initial materials and standards or corresponding regulations are changed; however, its validity will extend beyond the period of its effect.
3. If further requirements of national or EU legal regulations apply to the product, the Attest does not replace procedures and documents necessary for assessment of compliance with these regulations.



ATTEST
No. 472111404
Values obtained:

Material identification by FTIR method

Sample	Material identification
High-frequency level sensor RFLS-35N-2-CI – plastic part	Polytetrafluoroethylene – PTFE

Assessment of organoleptic properties

High-frequency level sensor RFLS-35N-2-CI (PTFE + stainless steel)

Food, contact conditions		Overdone drinking water, 100 °C / 2 hours	
Assessor No.	Unit	Odour	Flavour
1	level	0	0
2	level	0	0
3	level	0	0
4	level	0	1
5	level	0	0
6	level	1	2 (bitter)
Mean	level	0	0.5

Off-odour and off-taste scale:

0 = No perceptible off-odour or off-taste

1 = Just perceptible off-odour or off-taste (off-odour and off-taste determination is very difficult)

2 = Moderate off-odour or off-taste

3 = Strong off-odour or off-taste

4 = Very strong off-odour or off-taste

According to Commission Regulation (EU) 10/2011 the articles shall not cause a deterioration in the organoleptic characteristics of food

Identification of low-molecular substances by method TD-GC-MS

High-frequency level sensor RFLS-35N-2-CI – PTFE material

Substance name	CAS No	Ref No	Limit ¹⁾
No low-molecular substances restricted by SML were identified by TD-GC-MS method			

Note to the table:

¹⁾ Limit value according to Commission Regulation (EU) No 10/2011

Conditions for use of the Attest and associated information:

1. The Attest applies only to the sample tested by our laboratory.
2. The Attest remains in effect until production technology, initial materials and standards or corresponding regulations are changed; however, its validity will extend beyond the period of its effect.
3. If further requirements of national or EU legal regulations apply to the product, the Attest does not replace procedures and documents necessary for assessment of compliance with these regulations.





ATTEST No. 472111404

Overall migration determination, 100 °C / 2 hours

High-frequency level sensor RFLS-35N-2-CI – PTFE material

Food simulant	Unit	Value obtained ¹⁾		Uncertainty ²⁾	Limit ³⁾
		Single results	Average		
10 % ethanol	mg/ article	< 0.5; < 0.5; < 0.5	< 0.5	-	max. 10
3 % acetic acid	mg/ article	0.7; 0.8; 0.9	0.8	0.2	max. 10
Olive oil	mg/ article	0.8; 2.0; 1.7; 1.5	1.7	0.3	max. 10

Notes to the table:

- ¹⁾ Symbol „<“ means less than limit of detection of the analytical method.
- ²⁾ The reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor of k=2, providing a level of confidence of approximately 95%.
- ³⁾ Limit values according to Decree of Health Ministry No. 38/2001 Coll., as amended and according to Commission Regulation (EU) No 10/2011. Limit is expressed as mg/ dm² applying the total contact surface of the sensor and container, which is the sensor intended for.

**Specific migrations of metals and primary aromatic amines
according to Annex II of Commission Regulation (EU) No. 10/2011**

High-frequency level sensor RFLS-35N-2-CI – PTFE material

Parameter	Unit ¹⁾	Value obtained ²⁾	Limit ³⁾
Specific migration into 3% acetic acid, 100 °C / 2 hours			
Al	mg/kg	< 0.10	max. 1
Ba	mg/kg	< 0.05	max. 1
Co	mg/kg	< 0.005	max. 0.05
Cu	mg/kg	< 0.05	max. 5
Fe	mg/kg	< 0.10	max. 48
Li	mg/kg	< 0.01	max. 0.6
Mn	mg/kg	< 0.01	max. 0.6
Ni	mg/kg	< 0.01	max. 0.02 ⁴⁾
Zn	mg/kg	< 0.10	max. 5
Primary aromatic amines ⁵⁾	mg/kg	< 0.007	max. 0.01

Notes to the table:

- ¹⁾ Expressed as mg of element per kg of simulant
- ²⁾ Symbol „<“ means less than LOD (limit of detection) of the analytical method. The test results are expressed including the reported expanded uncertainty based on a standard uncertainty multiplied by a coverage factor of k=2, providing a level of confidence of approximately 95%.
- ³⁾ Limit values according to Commission Regulation (EU) No 10/2011
- ⁴⁾ The limit value valid from May 19, 2019
- ⁵⁾ Expressed as mg of aniline per kg of food stimulant

Conditions for use of the Attest and associated information:

- The Attest applies only to the sample tested by our laboratory.
- The Attest remains in effect until production technology, initial materials and standards or corresponding regulations are changed; however, its validity will extend beyond the period of its effect.
- If further requirements of national or EU legal regulations apply to the product, the Attest does not replace procedures and documents necessary for assessment of compliance with these regulations.





ATTEST No. 472111404

Assessment of stainless steel (sample No. 2)

Parameter	Unit	Value obtained	Uncertainty ¹⁾	Limit ²⁾
Content of selected elements				
Chromium	% w/w	16.9	1.7	max. 21.0
Nickel	% w/w	9.83	0.99	max. 14.0
Manganese	% w/w	1.56	0.16	max. 10.5
Evaluation of corrosion resistance				
Corrosion resistance	no corrosion stains			without corrosion

Notes to the table:

- ¹⁾ Uncertainty value – type B: 10 % rel. from the value obtained
- ²⁾ Limit value according to Decree of the Health Ministry No. 38/2001 Coll. as amended

Specific migration of selected elements into 0.5% citric acid, 100 °C / 2 hours; *1st and 2nd migration*

Parameter	Unit ¹⁾	Test result ²⁾			Limit ³⁾
		1 st migration	2 nd migration	∑ 1 st + 2 nd migration	
Ag	mg/kg	< 0.005	< 0.005	< 0.010	0.56
Al	mg/kg	< 0.10	< 0.10	< 0.20	35
Co	mg/kg	< 0.001	< 0.001	< 0.002	0.14
Cr	mg/kg	0.017±0.001	< 0.005	0.017±0.001	1.75
Cu	mg/kg	< 0.05	< 0.05	< 0.10	28
Fe	mg/kg	0.15±0.02	< 0.10	0.15±0.02	280
Mg	mg/kg	< 0.05	< 0.05	< 0.10	-
Mn	mg/kg	0.084±0.008	< 0.01	0.084±0.008	12.6
Mo	mg/kg	< 0.01	< 0.01	< 0.02	0.84
Ni	mg/kg	< 0.05	< 0.05	< 0.10	0.98
Sn	mg/kg	< 0.05	< 0.05	< 0.10	700
Ti	mg/kg	< 0.01	< 0.01	< 0.02	-
V	mg/kg	< 0.001	< 0.001	< 0.002	0.07
Zn	mg/kg	< 0.10	< 0.10	< 0.20	35
As	mg/kg	< 0.0005	< 0.0005	< 0.0010	0.014
Ba	mg/kg	< 0.05	< 0.05	< 0.10	8.4
Be	mg/kg	< 0.005	< 0.005	< 0.010	0.07
Cd	mg/kg	< 0.001	< 0.001	< 0.002	0.035
Hg	mg/kg	< 0.001	< 0.001	< 0.002	0.021
Li	mg/kg	< 0.01	< 0.01	< 0.02	0.336
Pb	mg/kg	< 0.005	< 0.005	< 0.010	0.070
Sb	mg/kg	< 0.005	< 0.005	< 0.010	0.28
Tl	mg/kg	< 0.00005	< 0.00005	< 0.00010	0.0007

Conditions for use of the Attest and associated information:

1. The Attest applies only to the sample tested by our laboratory.
2. The Attest remains in effect until production technology, initial materials and standards or corresponding regulations are changed; however, its validity will extend beyond the period of its effect.
3. If further requirements of national or EU legal regulations apply to the product, the Attest does not replace procedures and documents necessary for assessment of compliance with these regulations.





ATTEST
No. 472111404

Specific migration of selected elements into 0.5% citric acid, 100 °C / 2 hours;
3rd migration

Parameter	Unit ¹⁾	Test result ²⁾	Limit ⁴⁾
		3 rd migration	
Ag	mg/kg	< 0.005	max. 0.08
Al	mg/kg	< 0.10	max. 5
Co	mg/kg	< 0.001	max. 0.02
Cr	mg/kg	< 0.005	max. 0.250
Cu	mg/kg	< 0.05	max. 4
Fe	mg/kg	< 0.10	max. 40
Mg	mg/kg	< 0.05	-
Mn	mg/kg	< 0.01	max. 1.8
Mo	mg/kg	< 0.01	max. 0.12
Ni	mg/kg	< 0.05	max. 0.14
Sn	mg/kg	< 0.05	max. 100
Ti	mg/kg	< 0.01	-
V	mg/kg	< 0.001	max. 0.01
Zn	mg/kg	< 0.10	max. 5
As	mg/kg	< 0.0005	max. 0.002
Ba	mg/kg	< 0.05	max. 1.2
Be	mg/kg	< 0.005	max. 0.01
Cd	mg/kg	< 0.001	max. 0.005
Hg	mg/kg	< 0.001	max. 0.003
Li	mg/kg	< 0.01	max. 0.048
Pb	mg/kg	< 0.005	max. 0.010
Sb	mg/kg	< 0.005	max. 0.04
Tl	mg/kg	< 0.00005	max. 0.0001

Notes to the tables:

- 1) Expressed as mg of element per kg of food simulant
- 2) Symbol „<“ means LOD (limit of detection) of the analytical method.
- 3) The limit values for the sum of the first and second migration according to „A practical guide for manufacturers and regulators: Metals and alloys used in food contact materials and articles“, issued by European Directorate for the Quality of medicines & HealthCare.
- 4) The limit values according to „A practical guide for manufacturers and regulators: Metals and alloys used in food contact materials and articles“, issued by European Directorate for the Quality of medicines & HealthCare.

Conditions for use of the Attest and associated information:

1. The Attest applies only to the sample tested by our laboratory.
2. The Attest remains in effect until production technology, initial materials and standards or corresponding regulations are changed; however, its validity will extend beyond the period of its effect.
3. If further requirements of national or EU legal regulations apply to the product, the Attest does not replace procedures and documents necessary for assessment of compliance with these regulations.





INSTITUT PRO TESTOVÁNÍ A CERTIFIKACI, a. s.
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic
Testing Laboratory – D2

Attest No. 472111404

Sample description and identification:

ITC's number	Sample identification by client	Description of submitted sample
11404/1	High-frequency level sensor RFLS-35N-2-CI; material: PTFE	White plastic part – see the figure No. 1 on the page 2 of this attest
11404/2	High-frequency level sensor RFLS-35N-2-CI; material: stainless steel	Stainless steel part – see the figure No. 1 on the page 2 of this attest

Work requested:

Evaluation of hygienic properties of the sample according to Decree of Health Ministry No. 38/2001 Coll. *for articles intended into a contact with foodstuffs*, as amended, in compliance with the Law of Czech Republic No. 258/2000 Coll. *about protection of the public health*, as amended.

The evaluation of hygienic properties of the sample is based on European legislation in the sense of 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 Commission Regulation (EU) No. 10/2011 *on plastic materials and articles intended to come into contact with food*, as amended.

Opinions and interpretations:

The evaluated product “**High-frequency level sensor RFLS-35N-2-CI; materials: PTFE and stainless steel**” is intended for a direct contact with foodstuffs. According to the client the sensor will be a part of food containers with a minimal volume of 5 liters and short-time contact with all foodstuff types is presumed.

The requirements for products intended into direct contact with foodstuffs are given by Decree of the Health Ministry No. 38/2001 Coll., as amended (hereinafter referred to as Decree 38/2001), by Commission Regulation EU No. 10/2011 (hereinafter Regulation 10/2011) and by European Parliament and Council Regulation No. 1935/2004 (hereinafter Regulation 1935).

General requirements - Decree 38/2001, Regulation 10/2011 and Regulation 1935

The products intended to contact with foodstuffs shall be manufactured so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could: endanger human health or bring about an unacceptable change in the composition of the food or bring about a deterioration in the organoleptic characteristics thereof. The performed tests verified that the evaluated sample does not influence the organoleptic properties of the food (see the table on the page 3 of this attest). The constituent transferring is discussed further.

Requirements for plastic products - Decree 38/2001, Regulation 10/2011

Only the monomers and other basic substances listed in the Annex I to Regulation 10/2011 can be used for the manufacturing of the plastic products intended into contact with foodstuffs, complying with defined limitation. The client did not supply documentation declared the conformity of the raw material with the requirements for plastic composition. The identification of low-molecular substances by TD-GC-MS method was performed on the sample of PTFE material to verify the compliance of the above requirement. No low-molecular substances were identified by TD-GC-MS method.

Assessment of raw materials as required under the article 5 and the Annex I to Commission Regulation 10/2011 is not a part of this attest.

Plastic materials and articles shall not transfer their constituents to foodstuffs in quantities exceeding 10 milligrams per square decimetre of surface area of material or article (mg/dm^2) (limit of overall migration). The test results including the migration conditions are mentioned on the page 4 of this attest.

Conditions for use of the Attest and associated information:

1. *The Attest applies only to the sample tested by our laboratory.*
2. *The Attest remains in effect until production technology, initial materials and standards or corresponding regulations are changed; however, its validity will extend beyond the period of its effect.*
3. *If further requirements of national or EU legal regulations apply to the product, the Attest does not replace procedures and documents necessary for assessment of compliance with these regulations.*



INSTITUT PRO TESTOVÁNÍ A CERTIFIKACI, a. s.
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic
Testing Laboratory – D2

Attest No. 472111404

General restrictions on plastic materials and articles according to the Commission Regulation No. 10/2011/EC:

Materials and articles shall not release metals: Al, Ba, Co, Cu, Fe, Li, Mn, Ni and Zn and primary aromatic amines in foods or food simulants in quantities exceeding the specific migration limits set out in the Annex II to this Regulation. Compliance with the specific migration limit of these substances was verified experimentally and is shown in the table on the page 4 of this attest.

Requirements for metal products – Decree 38/2001

Requirements for metallic products are given by article 17. For the metallic articles production only the metals, alloys and solders stated in the Annex No. 8 can be used.

The corrosion resistance steels shall contain max. 21.0 % chromium, 14 % nickel and 10.5 % manganese. The composition of the stainless steel part was verified and is shown in the table on the page 5 of this attest. Stainless steel meets the requirements for its composition.

The products intended to come into contact with foodstuffs shall be food-resistant. The corrosion resistance was tested on the sample. The tested sample meets the requirements for corrosion resistance.

The migration of the selected metallic elements into 0.5% citric acid according to „A practical guide for manufacturers and regulators: Metals and alloys used in food contact materials and articles“, issued by European Directorate for the Quality of medicines & HealthCare was verified for the submitted sample. The test results including migration conditions are mentioned in the tables on the pages 5 and 6 of this attest. All measured values of specific migration meet the required limit values.

Tests results of migration tests meet the above mentioned requirements under following conditions:

- **Contact with all foodstuff types at temperatures up to 100 °C for up to 2 hours**
- **Ratio: 1 piece of sensor/1000 g (ml) of food (or more)**

The opinion expressed and interpretation made by:

Dipl. Ing. Šárka Kopečková, September 5, 2018

Conclusion:

The comparison of the obtained results with the limits of Decree No. 38/2001 Coll., as amended, of Commission Regulation (EU) No. 10/2011 and of the article 3 of European Parliament and Council Regulation No. 1935/2004 and evaluation of the conformity with these regulations are mentioned on the page 1 of this attest.

Dipl. Ing. Věra Vilímková
Head of the laboratory of analytical
chemistry and microbiology

Conditions for use of the Attest and associated information:

1. *The Attest applies only to the sample tested by our laboratory.*
2. *The Attest remains in effect until production technology, initial materials and standards or corresponding regulations are changed; however, its validity will extend beyond the period of its effect.*
3. *If further requirements of national or EU legal regulations apply to the product, the Attest does not replace procedures and documents necessary for assessment of compliance with these regulations.*