Endress+Hauser
People for Process Automation

EU Food Contact Material REG (EC) 1935/2004 Declaration of Compliance

Company

Endress+Hauser Conducta GmbH+Co. KG

Dieselstraße 24, 70839 Gerlingen, Germany

as a manufacturer of products for liquid analysis declares, that the product

Product

Smartec CLD18

Regulations

We declare that the above named product conforms to following European Regulations and is therefore **suitable for food contact**:

Regulation (EC)	1935/2004, Article 3, 5, 15, 17 (L231)
Regulation (EC)	2023/2006 (L 86)
Regulation (EU)	10/2011 (L 288)
Regulation (EC)	1895/2005 (L 302)
Law	§31 LFGB (German Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch)

The following process contact parts are used:

Process contact part	Extended order code	Material group	Material
Sensor housing	CLD18-****	Plastic	PEEK
O-ring	CLD18-****	Rubber	EPDM
Process Connection	CLD18-*bbb bbb≠GCP/LQP/MOP	Metal	Stainless steel 1.4435

Conditions of intended use

For use in accordance with product specifications.

Specification for intended use or limitations:

- All types of food: aqueous, acidic, alcoholic, lacteal, fatty and oily food,
- repeated use,
- OM6 (testing condition): Any food contact conditions at a temperature exceeding 40 °C, including high temperature applications up to 121 °C can be applied
- EPDM is not recommended to use in edible oils and fats, only in milk products with max. 8% of milk fat.

Further information

Plastic:

Following overall migration (OML) were checked:

Simulant	Test conditions	OML [mg/dm²]	Assessment
Acetic acid 3 %	4 h, 100 °C	≤ 10	Pass
Isooctane	4 h, 60 °C	≤ 10	Pass
Ethanol 95 %	6 h, 60 °C	≤ 10	Pass

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The following substances with a specific migration limit (SML) were used in plastics materials and tested:

CAS-No.	Substance name	Simulant	Test conditions	SML [mg/kg]	Assessment
345-92-6	4,4´-Difluoro-benzo-phenone	Acetic acid 3 % Ethanol 95 %	4 h, 100 °C 6 h, 60 °C	≤ 0.05	Pass
123-31-9	1,4-Dihydroxy-benzene	Acetic acid 3 % Vegetable oil	4 h, 100 °C 2 h, 175 °C	≤ 0.6	Pass
127-63-9	Diphenyl sulfone	Acetic acid 3 % Ethanol 95 %	4 h, 100 °C 6 h, 60 °C	≤ 3	Pass
102-09-0	Diphenyl carbonate	Ethanol 95 %	6 h, 60 °C	≤ 0.05	Pass

For the determination of all migration values a surface/volume ratio of 6 dm^2/kg was used.

The conditions of all migration tests correspond to OM6 or higher. Substitute migration tests for food simulant D2 were done with 95 % ethanol and isooctane. The test conditions for this substitute migration tests were selected according to DIN EN 1186-1:2002.

10% ethanol is covered by the test with 95% ethanol.

The simulants selected for specific migration correspond to the "worst case" determined by the test laboratory.

The results of the migration of various metals and primary aromatic amines for the plastics were below those pre-scribed in Regulation (EU) 10/2011, Annex II. These migrations tests were done under “worst case” conditions determined by the test laboratory.

All migration tests prescribed in Regulation (EU) 10/2011 were carried out three times and passed the evaluation of stability.

The bisphenol-A migration is below <0.1 mg/kg.

The plastic does not contain any substances that are subject to restrictions according to Regulation (EC) 1895/2005.

The following dual use additives were used in plastic materials:

- Sodium phosphates (E 339)

Rubber:

The EPDM material comply with the American 21 CFR 177.2600 and additionally comply with the recommendations of BfR XXI Cat. 1 concerning overall migration.

Metal:

The stainless steel 1.4435 have been tested according to the "Technical guide on Metals and Alloys used in food contact materials" of the "European Directorate for the Quality of Medicines & HealthCare" (EDQM) 1st Edition from 2013. It meets the requirements of the test specification.

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Additional information

The migration of various sulphones according to the recommendation of BfR part LI, polycyclic aromatic hydrocarbons (PAH), Primary aromatic amines (PAA) and Phthalate plasticizers was investigated and passed.

Non-intentionally added substances (NIAS):

To the best of our knowledge, no non-intentionally added substances (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.

Remarks

The product has to be cleaned before use.

This declaration of compliance is to emphasize that the customer is obliged to test the product with regard to its suitability in the application. This declaration of compliance is only valid for the listed product as supplied to customer.

For technical special products (TSP, model designation with modification no.) a declaration of compliance is available upon additional request.

Free marketing of goods in the EU:

The regulation EU 2019/515 of March 2019 obliges the EU member states to mutually recognize goods lawfully marketed in other member states.

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Dieselstraße 24, 70839 Gerlingen, Germany

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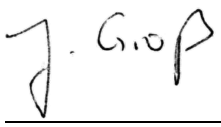

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