

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 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 351)
Regulation (EU)	10/2011 (L 245)
Regulation (EC)	1895/2005 (L 302)
Regulation (EU)	2024/3190 (L 250)
Law	§31 LFGB (German Food and Feed Code)

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
	CLD18-*bbb		
Process Connection	bbb≠GCP/LQP/MOP	Metal	Stainless steel 1.4435

Conditions of intended use Use in accordance with the product specifications.
Specifications for intended use and limitations:

- Suitable for all food types: aqueous, acidic, alcoholic, dairy, fatty and oily foods,
- suitable for repeated use,
- OM6 test conditions apply: Any food contact conditions at a temperature exceeding 40 °C, including high temperature applications up to 121 °C,
- 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 area-to-volume ratio of 6 dm²/kg was applied.

The conditions of all overall migration tests corresponded to OM6 or more severe test conditions. Substitute migration tests for food simulant D2 were performed using 95% ethanol and isooctane. The test conditions for these substitute tests were selected in accordance with DIN EN 1186-1:2002. The test with 95% ethanol is considered to be representative and covers the use of 10% ethanol.

The food simulants selected for specific migration testing represent the worst-case conditions as determined by the testing laboratory.

The migration levels of various metals and primary aromatic amines from the plastic materials were below the limits specified in Annex II of Regulation (EU) No. 10/2011. These migration tests were also conducted under worst-case conditions determined by the testing laboratory.

All migration tests required by Regulation (EU) No. 10/2011 were performed in triplicate and successfully met the stability evaluation criteria.

The plastic material does not contain any substances subject to restrictions under Regulation (EC) No. 1895/2005.

The following dual-use additive was used in the plastic materials:

- Sodium phosphates (E 339)

Rubber:

The EPDM material complies with the American 21 CFR 177.2600 and additionally conforms to requirements of the German Food and Feed Code (LFGB) and The Federal Institute for Risk Assessment (BfR) XXI/1, Category 4.

Metal:

Stainless steel 1.4435 has been tested in accordance with 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, 2013. It meets the requirements of the test specification.

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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.

Bisphenols

Bisphenols or bisphenol derivatives are neither used in our food contact materials nor intentionally added during the manufacturing process from us or our suppliers. We are conform to Regulation (EU) No. 2024/3190 on the use of Bisphenol A (BPA) and other Bisphenols and Bisphenol derivatives in the process contact rubber and polymer parts intended to come into contact with food.

Remarks

The product has to be cleaned before use.

The customer is obliged to test or otherwise evaluate the product with regard to its suitability in the application.

This declaration of conformity is only valid for the listed product in its delivery condition without further modification. No further suitability of the products for a specific purpose can be derived from this. In the case of enclosed adapter sets or replacement gaskets, the owner/user is responsible for the correct part installation as stated on the compliance declaration.

Since conditions of use are outside Endress+Hauser's control, Endress+Hauser makes no warranties, expressed or implied, and assumes no liability in connection with any use of this declaration.

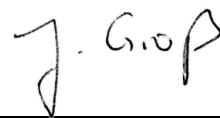
For technical special products (TSP, model designation with modification no.) a declaration of compliance is available upon additional request.

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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