

according to ASME BPE 2022

Company Endress+Hauser Conducta GmbH+Co. KG
Dieselstraße 24, 70839 Gerlingen, Germany

as a manufacturer of products for liquid analysis hereby aims to inform its customers of a Level 3 product change according to ASME BPE 2022, paragraph PM-2.2.3.3.

Subject Introduction of an EPDM sealing solution due to changes in compliance status of FFKM sealing compound

Effective Date This change is expected to become effective on February 1st, 2024.

Affected Products The following products will be affected by the change, as detailed with their respective order codes.

- | | |
|------------------------|---|
| Condumax CLS16 | CLS16-*****

Standard materials: Sensor 1.4435, seal FFKM |
| Condumax CLS16B | CLS16B-****cc**+ JEJGJ1J2J3J4LC

New product, soon replacing Condumax CLS16

cc (Materials)
20 Sensor 1.4435, seal FFKM
new Option 40 Sensor 1.4435, seal PEEK/EPDM |
| Condumax CLS16D | CLS16D-*****

Standard materials: Sensor 1.4435, seal FFKM |
| Memosens CLS16E | CLS16E-****cc+JEJGJ1J2J3J4LC

cc (Materials)
20 Sensor 1.4435, seal FFKM
new Option 40 Sensor 1.4435, seal PEEK/EPDM |

Change Information Endress+Hauser has been informed that changes in the sealing formulation and/or manufacturing process of our FFKM sealing are being made. Our supplier announced, that this is due to the possible restriction of PFAS in the United States and the European Union. These changes in manufacturing and formulation will result in the current sealing compound not being FDA-compliant. Our FFKM sealing solution will thereafter not be suitable for use in applications where FDA compliance is mandatory. We are aware that this change is highly impactful to customer products and processes.

- The Key Changes for our Products CLS16, CLS16B, CLS16D and CLS16E will be:
- Change in compliance status of the current FFKM sealing for applications where FDA compliance is mandatory (details see below).
 - Introduction of a new, reliable, and equally compliant sealing solution with EPDM and PEEK in process contact into CLS16B and CLS16E.
 - Introduction of a new product root Condumax CLS16B, fit to replace CLS16.

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Seal performance of the new EPDM compound has been assessed. We do not expect significant deviations under the conditions of intended use. Since this is a change in form and composition, please make sure that the new EPDM solution is suitable for your application.

The compliance status of the current and future sealing solutions has been checked. The future EPDM/PEEK sealing will meet or exceed the compliance requirements of the current ones. The following table shows more detailed information.

	Current FFKM sealing	Future EPDM/PEEK sealing
FDA	Complies with Regulation 21 CFR 177.2400(d) (1) and 21 CFR 177.2600 of the US-American Food and Drug Administration (FDA).	EPDM complies with Regulation 21 CFR 177.2600 of the US-American Food and Drug Administration (FDA). PEEK Complies with Regulation 21 CFR 177.2415 of the US-American Food and Drug Administration (FDA).
Regulation (EC) 1935/2004	Passed the migration and sensory requirements of the German Food and Feed Code (LFGB), The Federal Institute for Risk Assessment (BfR) XXI, Category 1, and Article 3 of the Regulation (EC) 1935/2004 for aqueous, alcoholic and fatty food.	EPDM passed the migration and sensory requirements of the German Food and Feed Code (LFGB), The Federal Institute for Risk Assessment (BfR) XXI, Category 1, and Article 3 of Regulation (EC) 1935/2004 for aqueous, acidic, alcoholic and fatty food. PEEK complies with the requirements of regulations (EC) 1935/2004, Articles 3, 5, 15, 17 and fulfills the migratory requirements of regulation (EC) 10/2011.
CN FCM GB 4806	Material is not listed in GB 4806.11 but complies with 21 CFR 177.2600 and REG (EC) 1935/2004. Migration tests required in GB 4806.11 were performed.	Conformity is still being assessed
USP Chapter 87	Biological reactivity tests (in vitro) shows no cytotoxic effects in all extracts.	
USP Chapter 88	Biological reactivity tests (in vivo) comply with the requirements of „Class VI“ (121°C)	
ADI-free	Is free of animal derived ingredients (ADI) and does not contain any raw materials derived from bovine or animal sources.	

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EU RoHS / China RoHS II	Fully complies with the Commission Delegated Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances (RoHS), as well as MIIT Order 32 (China-RoHS).
REACH- Regulation (1907/2006)	To our supplier's best knowledge and availability of information, their products fully comply with the provisions of Annex XIV "List of substances subject to Authorization" as well as of Annex XVII "Restrictions of certain Substances, Mixtures and Articles" in their latest version, respectively.

Price The market price of the devices listed above is not expected to change due to this.

Remarks This change notification does not exempt the customer from evaluating the product regarding its suitability for the intended use. This change notification is exclusively valid for the products / order codes listed above.

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