

according to ASME BPE 2024

Company	Endress+Hauser Conducta GmbH+Co. KG Dieselstrasse 24, 70839 Gerlingen, Germany
	as a manufacturer of products for liquid analysis aims to inform its customers of Level 2 product changes according to ASME BPE 2024, paragraph PM-2.2.3.3.
Subject	<ul style="list-style-type: none">A: Introduction of a new EPDM sealing material due to discontinuation of the current compound.B: Introduction of a new FKM sealing material due to discontinuation of the current compound.C: Introduction of a new silicone sensor seal with improved hygienic geometry and new silicone compound.
Effective date	This change is expected to become effective on January 1 st , 2026.
Affected products	The following products will be affected by the change, as detailed with their respective order codes.

Unifit CPA842
Spare parts CPA842 XPC0017

Affected ordercodes	CPA842-***aa****+bb aa = Changes in sealing material EPDM, option 030 >> E1 (A) aa = Changes in sealing material FKM, option 030 >> F1 (B) aa = Discontinuation of silicone O-ring, option 030 >> S2 (C) aa = Introduction of new silicone gasket, option 030 >> S1 (C) bb = Changes in declarations and certificates, option 580 >> JE, JG, J1, J2, J3 (A+B+C)
	XPC0017-F+aabbcc aa = Changes in declarations and certificates option 580 >> JE, JG, J1, J2, J3 (A+B+C) bb = Changes in sealing material FKM, option 605 >> M5, M6 (B) cc = Changes in sealing material EPDM, option 620 >> Q1, R1 (A) cc = Changes in sealing material FKM, option 620 >> R2, R7 (B) cc = Discontinuation of silicone O-ring, option 620 >> R5 (C) cc = Introduction of new silicone gasket, designation to be determined (C)

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Change information

A+B: Endress+Hauser has been informed that the EPDM and FKM compounds currently used in CPA842 and XPC0017 are being discontinued. This creates the necessity for Endress+Hauser to introduce new EPDM and FKM sealing materials as a replacement. The replacement sealing materials will be sourced from the same supplier as the ones before. Nonetheless, we are well aware that this change could have an impact on customer products and processes.

C: For the purpose of improved cleanability of Cleanfit CPA842, the current sensor seal will be replaced. A new molded gasket will replace the current silicone O-ring. This requires changes to the silicone compound as well as the manufacturing process. Since this is a significant change, a new option will be introduced with this change.

The **key changes** for our products CPA842 and XPC0017 will be:

- Change of the EPDM material of the seals (A).
- Change of the FKM material of the seals (B)
- Introduction of a new silicone sensor seal for improved cleanability as a new option (C)
- Discontinuation of the current silicone sensor seal (C)
- Change in compliance status of the EPDM, FKM and silicone sealing materials (A+B+C; details see below).

The seal performance of the new EPDM and FKM compounds has been assessed. We do not expect significant deviations under the conditions of intended use. Performance of the new silicone seal is still being assessed. However, we expect a minor decrease in the maximum allowable pressure at high temperatures (140 °C).

The compliance status of the current and future seals have been checked. The future EPDM, FKM and silicone sealings are comparable to the current one regarding compliance requirements. The following tables show more detailed information.

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Compliance information on EPDM sealings		
Compliance	Current EPDM sealings	Future EPDM sealings
FDA 21 CFR	complies with Regulation 21 CFR 177.2600 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 complies to Article 3 of Regulation (EC) 1935/2004 for aqueous, alcoholic and fatty food.	meets relevant requirements of Regulation (EC) No 1935/2004 and complies to Category 4 described in BfR Recommendation XXI/1.
CN FCM GB 4806	Complies to GB 4806.1. Migration tests required in GB 4806.11 were performed. Suitable for repeated use in aqueous, acidic, alcoholic, lacteal, fatty and oily food.	Complies to GB 4806.1-2016, GB 4806.11-2023 and GB 9685-2016. It is suitable for aqueous, acidic, alcoholic with ≤ 50 % EtOH and lacteal food.
3-A Sanitary	Complies with the test requirements of „3-A Sanitary Standards for Multiple-Use Rubber and Rubber-Like Materials Used as Product Contact Surfaces in Dairy Equipment, Number 18-03“ Class I (Sterilization Temperature up to 149°C/300°F)	
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.	
EU RoHS / China RoHS	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).	
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 Authorisation" as well as of Annex XVII "Restrictions of certain Substances, Mixtures and Articles".	

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Compliance information on FKM sealings		
Compliance	Current FKM sealings	Future FKM sealings
FDA 21 CFR	complies with Regulation 21 CFR 177.2600 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 Regulation (EC) 1935/2004 for aqueous, alcoholic and fatty food.	
CN FCM GB 4806	Complies to GB 4806-1. Migration tests required in GB 4806.11 were performed. Suitable for repeated use in aqueous, alcoholic, lacteal, fatty and oily food. Not suitable for acidic food.	Compliance is still being assessed.
3-A Sanitary	Complies with the test requirements of „3-A Sanitary Standards for Multiple-Use Rubber and Rubber-Like Materials Used as Product Contact Surfaces in Dairy Equipment, Number 18-03” Class I (Sterilization Temperature up to 149°C/300°F)	
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.	
EU RoHS / China RoHS	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).	
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 Authorisation" as well as of Annex XVII "Restrictions of certain Substances, Mixtures and Articles" as of 11 April 2022 (last amended by Commission Regulation (EU) 2022/586)	

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Compliance information on silicone sealings

Compliance	Current silicone sealings	Future silicone sealings
FDA 21 CFR	complies with Regulation 21 CFR 177.2600 of the US-American Food and Drug Administration (FDA).	
Regulation (EC) 1935/2004	complies to Article 3 of Regulation (EC) 1935/2004 for aqueous, alcoholic and fatty food.	meets relevant requirements of Regulation (EC) No 1935/2004 and complies to recommendations of BfR No. XV chapter III.
CN FCM GB 4806	silicones are not regulated by GB 4806. We expect no harmful effects in food contact.	
3-A Sanitary	Information not provided by our supplier	
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.	
EU RoHS / China RoHS	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).	
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 Authorisation" as well as of Annex XVII "Restrictions of certain Substances, Mixtures and Articles" as of 11 April 2022 (last amended by Commission Regulation (EU) 2022/586)	

Price	The market price of the devices listed above is not expected to change due to this change.
Validity	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.
Remarks	The product has to be cleaned before use.

Gerlingen, Germany, 2025-06-30

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