

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	- 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 Version for clean utilities, discontinuation of the current EHEDG version. - D: Introduction of new order option “EHEDG EL Class I certificate” - E: Discontinuation of several process connections and a rinse connection.
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.

Cleanfit CPA875
Spare parts CPA875 XPC0001

Affected ordercodes	CPA875-****a*bbcd*A+eeff a = Changes in sealing material EPDM, option 040 >> E (A) a = Changes in sealing material FKM, option 040 >> F (B) bb = Discontinuation of process connections clamp 2 ½”, Neumo BioConnect DN65 and dairy fitting DIN 11851 DN65, option 030 >> CC, EF, MB (E) c = Discontinuation of rinse connection service chamber BioConnect DN6, option 070 >> 5 (E) d = Discontinuation of EHEDG Class I Version, option 080 >> A (C) d = Introduction of new versions for clean utilities,option 080 >> U (C) ee = Changes in declarations and certificates, option 580 >> JE, JG, J1, J2 (A+B+C) ff = Introduction of new option “EHEDG EL Class I certificate”, option 590 >> LC (D) XPC0001-a+*****bb**ccdd a = Introduction of new versions for clean utilities, designation to be determined (C) bb = Changes in declarations and certificates, option 580 >> JE, JG, J1, J2, J3 (A+B+C) cc = Changes in sealing material FKM, option 605 >> PK (B) dd = Changes in sealing material EPDM, option 620 >> QA, QF, QI (A) dd = Changes in sealing material FKM, option 620 >> QB, QG, QJ (B)
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information**

A + B: Endress+Hauser has been informed that the EPDM and FKM compounds currently used in CPA875 and XPC0001 are being discontinued. This creates the necessity for Endress+Hauser to introduce new EPDM and FKM sealing materials as a replacement. Seal performance of the new EPDM and FKM compounds has been assessed. We do not expect significant deviations in form, fit and function under the conditions of intended use. Since this is a change in composition, please make sure that the new sealing solutions are suitable for your application.

The compliance status of the current and future seals have been assessed. The future EPDM and FKM seals are comparable to the current ones regarding compliance requirements. The following tables show more detailed information. 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 + D: Due to increased requirements for EHEDG certification, the EHEDG version of the Cleanfit CPA875 will be discontinued. Future product versions will be segmented with regards to compliance requirements. The CPA875 process type will continue to meet the highest requirements of our customers in the pharmaceutical, life sciences as well as food & beverage industries. A utilities type will be introduced to cover lower requirements in adjacent processes. The utilities versions will be able to quickly respond to changes in applicable legislation and certification requirements. An EHEDG EL Class I certificate will still be available, but it needs to be explicitly ordered via the respective option.

E: Due to changing market acceptance, several process connections and rinse connections will be discontinued. These Connections will still be available upon request as technical special products (TSP) in the future.

The **key changes** for our products CPA875 and XPC0001 will be:

- Change of the EPDM material of the seals. (A)
- Change of the FKM material of the seals. (B)
- Change in compliance status of the EPDM and FKM sealing materials (A+B; details see below).
- Discontinuation of the current EHEDG version. (C)
- Introduction of a new version for clean utilities. (C)
- Introduction of new order option “EHEDG EL Class I certificate” (E)
- Discontinuation of several process connections and a rinse connection. (D)

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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.	
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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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Price	The market price of the devices listed above is expected to undergo minor changes depending on the version selected in option 080.
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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