

## 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** Introduction of a new EPDM sealing material due to discontinuation of the current compound.

**Effective date** This change is expected to become effective on September 1<sup>st</sup>, 2026.

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

### Memosens CLS82E

**Affected ordercodes** CLS82E-\*\*aa\*\*  
a = Changes in sealing material EPDM, option 020 >> NA, NB

**Change information** Endress+Hauser has been informed that the EPDM compound currently used for the process seal of CLS82E with process connections DN25 and DN25 B.Braun port is being discontinued. This creates the necessity for Endress+Hauser to introduce a new EPDM sealing material as a replacement. Seal performance of the new EPDM compound has been assessed. We do not expect deviations in form, fit and function under the conditions of intended use. Since this marks a change in composition, please make sure that the new sealing solution is suitable for your application.

The compliance status of the current and new seals have been assessed. The new EPDM seals are comparable to the current ones regarding compliance requirements. The following table shows more detailed information. The new sealing materials will be sourced from the same supplier as the current ones. Nonetheless, we are well aware that this change could have an impact on customer products and processes.

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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”.	

**Price** The market price of the devices listed above is not expected to change due to the matter described herein.

**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.

Gerlingen, Germany, 2026-02-17

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