

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 aims to inform its customers of a Level 2 product change according to ASME BPE 2022, paragraph PM-2.2.3.3.
Subject	Introduction of a new FFKM chip seal due to changes in compliance status of FFKM sealing compound
Effective Date	This change is expected to become effective on December 15th, 2024 .
Affected Products	The following products will be affected by the change, as detailed with their respective order codes. Memosens CPS47E CPS47E-*****+aa aa = Changes in Declarations and Certificates (JE, JG, J1, J2, LB, LC) Memosens CPS77E CPS77E-*****+aa aa = Changes in Declarations and Certificates (JE, JG, J1, J2, LB, LC)
Change Information	<p>Endress+Hauser has been informed that changes in the formulation and/or manufacturing process of our chip seal 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 chip seal compound not being FDA-compliant. Therefore, we are sourcing our chip seal from a different supplier, going forward. We are aware that this change could have an impact on customer products and processes.</p> <p>The key changes for our products CPS47E and CPS77E will be:</p> <ul style="list-style-type: none">▪ Change of the FFKM material of the FFKM chip seal.▪ Change in compliance status of the FFKM chip seal for applications where FDA compliance is mandatory (details see below). <p>Seal performance of the new FFKM compound has been assessed. We do not expect significant deviations under the conditions of intended use. Since this is a change in composition, please make sure that the new FFKM solution is suitable for your application. The compliance status of the current and future chip seal have been checked. The future FFKM seal will be comparable to the current one regarding compliance requirements. The following table shows more detailed information.</p>

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Conformity	Current FFKM chip seal	Future FFKM chip seal
FDA	Complies with regulation 21 CFR 177.2600 and meets the extraction requirements acc. to regulation 21 CFR 177.2600 (e) - (f) and 21 CFR 177.2400 (d)(1) of the Food and Drug Administration (FDA).	Complies with the formulation and extraction requirements acc. to 21 CFR 177.2400 (a) - (d) of the US-American Food and Drug Administration (FDA).
Regulation (EC) 1935/2004	Complies with regulation 21 CFR 177.2600 and the recommendations of BfR XXI Cat. 1 concerning overall migration.	Complies with regulation 21 CFR 177.2400 (a) - (d) and the recommendations of BfR XXI Cat. 1 concerning overall migration.
USP Chapter 87	Biological reactivity tests (in vitro) show 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 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 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.

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