

Traceability for Products in the Pall Food Contact Compliant Portfolio ("W-code")

Products within the Food Contact Compliance (FCC) portfolio are manufactured in compliance with EU directive 2 with Annex I of Commission Regulation (EU) Number 10/2011, relating to plastic materials and articles intended to come into contact with food (excluding seals).

Additionally, this portfolio of products is manufactured applying the principles of Good Manufacturing Practice (GMP) for materials and articles intended to come into contact with food, as detailed in EC Regulation Number 2023/2006. This is reflected in the documented quality assurance systems at the manufacturing sites, as specified in Article 5.

The Declaration of Compliance documents for the FCC portfolio state that the sites of manufacture are certified to ISO 9001: 2015.

ISO 9001: 2015 8.5.2 states the following three requirements for identification and traceability:

- Use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.
- Identify the status of outputs with respect to monitoring and measuring requirements throughout production and service provision.
- Control the unique identification of the outputs when traceability is a requirement and retain documented information to enable traceability.

As specified in Articles 6 and 7 of EC Regulation Number 2023/2006 our manufacturing sites have effective quality control systems and maintain auditable documentation.

Declarations of Compliance for these products may be found at <u>Compliance</u> <u>Documentation for Food Contact Applications</u>.

Additional quality documentation related to food contact compliance may be found at the <u>Quality at Pall</u> website.

Should you have additional questions related to food contact compliance or product traceability please contact our team at FB_QARA_Compliance@pall.com.

Prepared by Pall Quality Assurance and Regulatory Affairs

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To the best of our knowledge this information is accurate as of the date of issuance. However, these statements are subject to change as new information becomes available. We recommend that you periodically confirm this information.

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