

Summary - Material of Construction Documentation

This document provides guidance for allowing Vendor's Material of Construction. Vendor-supplied documentation of material of construction is generally sufficient documented evidence for confirming that a specified material has been used in construction of the delivered system or component.

Materials of Construction for critical components (e.g., product contact) in both manufacturing and utility systems should be suitable for their intended use, in that they should:

- Be compatible with the product and any cleaning, passivating, sanitising / sterilizing agents.
- Be smooth and cleanable (where required).
- Be resistant to temperature extremes (if applicable).
- Not have Particle release (be low or non-fibre shedding).
- Not contribute foreign substances to the product.
- Be non-absorptive.
- Meet surface finish levels, where required and specified.

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The manufacturer is allowed to transfer onto this inspection certificate relevant test results obtained by specific inspection, provided that the manufacturer operates traceability procedures and can provide the corresponding inspection documents required.

Risk of impact to product quality due to the MOC of the component (higher risk = greater documentation requirement) Agreement on the required level of documentation for the materials of construction (MOC) needed to be supplied by the manufacturer (or their intermediary), should be reached early in the Design/Procurement phase for systems and components being purchased and built into the purchase specifications.

It is important to note that while classification of a metal may be determined, it would not be expected that specific alloys within metal classes (e.g. 304, 316L Stainless Steel) could be identified using the described visual identification methods. It is recommended that if the metal class has been determined via visual inspection, that it be documented along with the justification for the material's suitability for current use.

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