

Shelf Life and Storage Conditions of Allegro™ Single Use Systems

This statement is to confirm that Allegro single-use systems (SUS) are generally subject to a two-year shelf life from the date of manufacture when the following recommended storage conditions are adhered to. However, a shorter shelf life may be assigned to systems that contain sensors and/or newly developed components. In these cases, the shelf life of the SUS will be shortened to not exceed the shelf life of the component with the shortest shelf life.

Storage conditions:

- 1 Store in clean, dry conditions between 0 and 30 °C without exposure to irradiation sources such as direct sunlight.
- 2 Do not remove from the packaging until just before installation.
- 3 Exercise care when handling to avoid physical damage.
- 4 Refer to "Assembly and Installation Procedures for Pall Allegro Single Use Systems" instruction for use (reference number: USD 2421b).
- 5 Inspections and, where applicable, integrity testing are recommended prior to use.

Appropriate junction test validation has been undertaken to allow the claim on Allegro Single Use Systems. The integrity of any connections and joints used to create the product fluid path has been evaluated during the design and engineering steps, on new joints as well as on two-year-old real time aged and accelerated aged representative junctions. The validation package consists of tensile and pressure tests on the joints and visual inspection, post gamma. A risk assessment approach has been used to allow comparison of similar components and materials.

For Single Use Systems containing Allegro Film or Allegro TK8 film, shelf life testing has also been performed on the film and representative bag ports, post gamma. The shelf life validation package consists of seal strength, mechanical properties of the film and integrity testing.

System expiry date is recorded on the product packaging labels, (both on the box and inner bagging), and on the Certificate of Quality supplied with each batch.

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

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