

Shelf-Life and Recommended Customer 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. 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.

For SUS containing Allegro film or Allegro TK8 film, shelf-life testing has also been performed on the film and representative biocontainer ports, post gamma irradiation (worst-case dose of 50 kGy). The shelf-life validation package consists of seal strength, mechanical properties of the film and integrity testing.

Sterility testing has been carried out on sample sterility master sets, post real time aging exceeding two years. All results were negative, indicating sterility of the fluid paths had been maintained over the aged time period of the product.

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.

We recommend the following general storage conditions in order to maintain satisfactory performance during the shelf-life period:

- 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” Instructions For Use (IFU) (reference number: USD 2421b).
- 5 Inspections and, where applicable, integrity testing are recommended prior to use.

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.

Prepared by Pall Quality Assurance and Regulatory Affairs for Biotechnology

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Author: Sofie Vanlaer

Signature 



Corporate Headquarters

Port Washington, NY, USA
+1 800 717 7255 toll free (USA)
+1 516 484 5400 phone

European Headquarters

Fribourg, Switzerland
+41 (0)26 350 53 00 phone


Asia-Pacific Headquarters

Singapore
+65 6389 6500 phone

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Contact us at www.pall.com/contact

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