BIOTECH

Statement of Compliance

USTR 3484

Shelf-Life and Recommended Customer Storage Conditions for 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 other short shelf-life 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, 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.

The 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 'Guidance for Receipt, Storage, Unpacking and Handling of Pall's Allegro Single-Use Systems' (reference number: USD 3508, available on the Instructional Documentation page)' and the abbreviated, printed version (reference number: USD 2421c), a copy of which is placed in each SUS box.

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.

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