

Certificate of Conformance

This certifies that **HELAPET filters:** - **FH90072**
Lot Number: - **24681 B 40196**

Have been manufactured in a controlled environment. **HELAPET** operates with a certified and independently audited Quality Management System to the requirements of BS EN ISO 13485 current certified version Certificate No.MD78785.

Materials of Construction

All components of this filter are manufactured from materials suitable for contact with food and conform to the biological safety requirements laid down in the current USP Class VI - 121°C Plastics. They also conform with the requirements laid down for non fibre releasing filters as laid down in the United States FDA Title 21 CFR 211.72 and 210.3(b), (6).

The filters also meet the **HELAPET** quality control and assurance standards.

Product Integrity

Samples from this product lot have successfully passed:

A non-destructive integrity test to ≥ 70 psi for one minute.

Airflow rate – ≥ 5 L/min @ 10psi.

WEP - ≥ 28 psi

Sterilisation

All filters from this Lot have been sterilised by ETO – Batch: **24681 B 40196**.



Quality Assurance

08.02.2023

Date of Manufacture

Detailed data of specific tests performed are maintained in the product Lot records and are available for review.