

**1. Part Number:** 8079A-450

**2. Product Information:**

Description: Sterile Bag Stand-Up 450ml

Use: Single use, disposable sampling bags

Material of Construction: Thermoplastic laminate

- Conforms to FDA 21 CFR 177.1520
- Conforms to EU 10/2011
- BSE/TSE free

Closure Type: Attachment with 2 round wires

Bag Dimensions: 114 x 229mm

Thickness of Bag: 89 microns

Nominal Bag Volume: 400ml

Method of Sterilisation: Sterility is provided by irradiation. The sterilization dose ensuring a sterility assurance level (SAL) of  $10^{-3}$  has been established according to ISO 11137.

Pyrogens: This product is non-pyrogenic at the endotoxin limit of 2.15 EU/device. Nonpyrogenicity is supported by endotoxin testing of randomly selected samples using the Limulus amoebocyte lysate (LAL) gel assay according USP-NF <85> and <161> guidelines.

Packaging: 1000 bags per case (4 x 250)

Recommended Storage Conditions: Dry and ambient temperature

Shelf Life: 5 years

ATEX: This product has not been ATEX tested

**3. Country of Origin:** Made and packed in Canada.

**4. Repeated Use:** This is a single-use, disposable product and should not be re-used.

**5. Approval:**

Signed:



Name: Kuldeep Flora

Position: Quality Manager

Date: 14-Mar-24

Note: The information given in this document has been given to us by our suppliers and is passed on in good faith, we believe the information to be correct.