

Specification Sheet

Specification Number: 8080A-450

Revision: 01
Date Issued: 7-Oct-20

1. Part Number: 8080A-450

2. Product Information:

Nominal Bag Volume:

Description: PureBag 450ml - Sterile

Use: Single use, disposable sampling bags

Material of Construction: Light Density Polyethylene (LDPE) - virgin

Conforms to FDA CFR 177.1520

• BSE/TSE free

Closure Type: 2 steel wires (non product contact)

• Covered with FDA approved pressure sensitive tape with a

backing of polypropylene or PVC

Bag Dimensions: 114 x 229mm

Thickness of Bag 62 microns

Method of Sterilisation: Sterility is assured due to extrusion temperatures exceeding 220°C

450ml

which eliminates any present bacteria. During manufacturing all bags are sealed at both top and bottom in a continuous format before being cut into individual bags. This method assures that the bag's interior will never come in contact with its surroundings. Periodic validation tests, based on USP 34 – Sterility testing, are performed in the manufacturing facility to guaranty the sterility of

the processes.

Packaging: 1000 bags per case (2 x 500)

Recommended Storage Conditions: Dry and ambient temperature

Shelf Life: 5 years from the date of manufacture

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: 7-Oct-20

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.