

1. Part Number: 8080A-1200**2. Product Information:**

Description: PureBag 1200ml - Sterile

Use: Single use, disposable sampling bags

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

- Conforms to FDA CFR 177.1520
- Conforms to EU 10/2011
- 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 382mm

Thickness of Bag: 63 microns

Nominal Bag Volume: 1200ml

Method of Sterilisation: Sterility is provided by dry heat during extrusion of the plastic at temperatures exceeding 220°C (428°F). The approach ensures a sterility assurance level (SAL) of 10⁻³. Continued process effectiveness is demonstrated through periodic sterility testing. Sterility testing follows the USP-NF <71> guideline.

Pyrogens: This product is non-pyrogenic at the endotoxin limit of 2.15 EU/device. Non-pyrogenicity 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 (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: 12-Jul-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.