

## Specification Sheet

Specification Number:9053H-50SRevision:01Date Issued:21-Sep-21

**1. Part Number:** 9053H-50S

### 2. Photograph:



#### 3. Product Information:

Description: SteriWare® ULTRA Ladle 50ml – Sterile

Use: Double bagged, single use, disposable Ladle

Material of Construction: 100% High Density Polyethylene (HDPE)

• Conforms to FDA CFR 177.1520

Conforms to EU Regulations 10/2011

• Conforms to EC Regulations 1935/2004

· Conforms to USP Class VI

• Conforms to USP 661

• Certified BSE/TSE free

Method of Construction: Single piece, injection moulded

Nominal Length 260mm

Diameter of cup: 48mm

Nominal volume 50ml

Nominal Weight of Sampler: 16g

Graduation Marks: No

Moulding Environment: Class 100,000 Cleanroom
Packing Environment: Class 10,000 Cleanroom

Bags: - Double Bagged, heat-sealed PE/PET bag.

- Inner bag printed with batch information

Outer Packaging: Cardboard box

Box Liner: LDPE bag

Quantity per Box: 40

Method of Sterilisation: Gamma Irradiation (25-45kGy)
Recommended Storage Conditions: Dry and ambient temperature

Shelf Life: 5 years from the date of manufacture
ATEX: This device has not been ATEX tested



### Sampling Systems Ltd.

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**4. Change Control:** Sampling Systems operates a policy of continual improvement.

To be kept informed of all major changes to any product in the SteriWare range please email your contact details to

change.control@sampling.com

**5. Country of Origin:** Made and packed in the UK.

**6. Repeated Use:** This is a single-use, disposable product. Repeated use will lead to

failure.

**7. Approval:** Signed:

Name: Kuldeep Flora
Position: Quality Manager

Date: 21-Sep-21