


<http://www.steris-ast.com>

Certificate of Irradiation

Date Issued: 06-Nov-2023

UK32S12768259-1-1

This is to certify that Bradford Synergy Health PLC, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products
EN ISO 13485 Quality System - Medical Devices

Sampling Systems Ltd
4 & 5 Forge Mills Park
Station Road
Coleshill
Warwickshire B46 1JH
UNITED KINGDOM

Order Information

Account Number:	100494
Synergy Health Sales Part Reference:	1108546
Customer Reference Number:	74894
Product Description:	FAMILY 1
Validation Reference:	1.0229
Quantity Received:	12
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	THU 2 NOV 2023
Other Process Details:	BATCH 116224 2 PLT 48 BOXES BATCH 116166 2 PLT 48 BOXES BATCH 116285 1 PLT 42 BOXES BATCH 116218 1 PLT 23 BOXES BATCH 110445 4 PLT 96 BOXES BATCH 116162 1 PLT 54 BOXES BATCH 116224 1 MIXED PLT 2 BOXES BATCH 116166 1 MIXED PLT 21 BOXES BATCH 116629 1 PLT 16 BOXES

Irradiation Data

Date and Time of Irradiation:	03-NOV-2023 16:18
Calculated Minimum Dose kGy:	27.7
Calculated Maximum Dose kGy:	39.1

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

Processing Site: Roysdale Way, Euroway Trading Estate, Bradford, BD4 6SE Phone No: +44 (0) 1274 686011

Registered Office: Ground Floor Stella, Windmill Hill Business Park, Whitehill Way, Swindon, Wiltshire SN5 6NX, UNITED KINGDOM
Company Registered in England and Wales No: 01771333 VAT Number: GB 813038069

Certificate of Conformity

Konformitätsbescheinigung
Certificat de Conformité
Certificato di conformità
Certificado de conformidad
Certificado de Conformidade



**SAMPLING
SYSTEMS**

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Part Number	9286H – 500S
Description	SteriWare® ULTRA Volumetric Scoop
Batch Number	116224
Date of Manufacture	25 October 2023
Expiry Date	25 October 2028
Material	HDPE (High Density Polyethylene)
Certificate Issued	12 November 2023

- We confirm that the goods are manufactured with HDPE that conforms to:
 - FDA 21 CFR 177.1520
 - USP Class VI
 - EU 10/2011
 - EC 1935/2004
- Products manufactured from the HDPE polymer used to manufacture this batch have been tested and meet the requirements of USP 661.
- The HDPE resin used in the manufacture of the above products is BSE/TSE free. During manufacture this item does not come into contact with any products or processes that may pose a BSE/TSE risk.
- These goods are manufactured in a class 100,000 Cleanroom.
- These goods are packed in a class 10,000 Cleanroom.
- Each item is double bagged.
- This product is designed for single use only. It must not be used multiple times.
- The information detailed above has been given to us by our suppliers, it is passed on in good faith and is to the best of our knowledge correct.

For and on behalf of Sampling Systems Ltd.

Für und im Namen von Sampling Systems Ltd.

Pour et au nom de Sampling Systems Ltd.

Da e per conto di Sampling Systems Ltd.

En nombre y por cuenta de Sampling Systems Ltd.

Por e em nome de Sampling Systems Ltd.

Kuldeep Flora
Quality Manager