



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

Certificate of Irradiation

Date Issued: 16-Apr-2020

UK32S12422839-1-1

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:	1120714
Customer Reference Number:	S20-71582
Product Description:	Family 2
Validation Reference:	1.0270
Quantity Received:	14
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	THUR 09 APR 2020

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


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Other Process Details:

BATCH 068468 1 PLT 49 BOXES
BATCH 069307 1 MIXED PLT 20 BOXES
BATCH 069306 1 MIXED PLT 20 BOXES
BATCH 068460 2 MIXED PLTS 50 BOXES
BATCH 068075 2 MIXED PLTS 90 BOXES
BATCH 068474 1 PLT 50 BOXES
BATCH 068462 1 PLT 36 BOXES
BATCH 068461 1 PLT 36 BOXES
BATCH 068462 1 MIXED PLT 14 BOXES
BATCH 068461 1 MIXED PLT 14 BOXES
BATCH 068465 1 PLT 36 BOXES
BATCH 068456 1 PLT 36 BOXES
BATCH 068465 1 MIXED PLT 14 BOXES
BATCH 068456 1 MIXED PLT 14 BOXES
BATCH 068075 1 MIXED PLT 20 BOXES
BATCH 068469 1 MIXED PLT 25 BOXES
BATCH 068463 1 MIXED PLT 5 BOXES
BATCH 068469 1 MIXED PLT 25 BOXES
BATCH 068463 1 MIXED PLT 5 BOXES
BATCH 068455 1 PLT 50 BOXES

Irradiation Data

Date and Time of Irradiation:	16-APR-2020 14:19
Calculated Minimum Dose kGy:	26.4
Calculated Maximum Dose kGy:	37.9

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

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Certificate of Conformity

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



Page 1 of 2

Part Number	8015A – 170S
Description	SteriWare® Micro-Spatula
Batch Number	068075
Date of Manufacture	31 March 2020
Expiry Date	31 March 2025
Material	Polystyrene (PS)
Certificate Issued	03 April 2020

English

- We confirm that the goods are manufactured with Polystyrene that conforms to:
 - FDA CFR 177.1640
 - EU regulations 10/2011
 - EC regulations 1935/2004
- The Polystyrene 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 moulded and packed in a class 100,000 cleanroom. They are individually packed.
- 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.

Deutsch

- Wir bestätigen, dass die Artikel aus PS (Polystyrol), das FDA CFR 177.1640 entspricht, hergestellt sind..
- Das PS (Polystyrol) Harz, das für die Herstellung obenstehender Produkte verwendet wurde, ist BSE/TSE-frei. Bei der Herstellung gelangt dieser Artikel nicht mit irgendwelchen Produkten oder Prozessen, die eine BSE/TSE-Gefahr darstellen, in Kontakt.
- Diese Artikel wurden in einem Reinraum der Klasse 100.000 geformt und verpackt. Die Artikel sind einzeln verpackt..
- Dieser Artikel darf nur einmal verwendet werden. Er darf nicht mehrmals benutzt werden.
- Die obenstehenden Informationen wurden uns von unseren Zulieferern mitgeteilt und werden in Treu und Glauben nach unserem jüngsten Wissensstand weitergeleitet.

Français

- Nous certifions que les articles sont fabriqués à partir de Polystyrène conforme à la norme FDA CFR 177.1640.
- La résine (PS) utilisée dans la fabrication des articles ci-dessus ne contient aucune trace de BSE ni d'EST. Lors de la fabrication, cette matière n'entre pas en contact avec des produits ou des procédés qui peuvent présenter un risque d'ESB / EST.
- Ces produits sont moulés et emballés dans une salle blanche de classe 100.000. Ils sont emballés individuellement.
- Ce produit est conçu pour un usage unique. Il ne doit pas être utilisé plusieurs fois.
- Les informations mentionnées ci-dessus ont été données par nos fournisseurs, elles sont transmises en bonne foi et, au meilleur de notre connaissance, sont exactes.

Italiano

- Si conferma che la merce è prodotta in Polistirene certificata da FDA CFR 177.1640
- La Polistirene resina utilizzata nella produzione dei prodotti è certificata BSE/TSE free. Durante la produzione l'articolo non è entrato in contatto con nessun prodotto o processo che possa causare un rischio BSE/TSE
- Questa merce è stata prodotta e imballata in camera bianca classe 100,000. E' stata confezionata singolarmente.
- Il prodotto è stato concepito solo per un singolo utilizzo. Non può essere utilizzato più di una volta.



Sampling Systems Ltd.

4-5 Forge Mills Park, Coleshill, Warwickshire. B46 1JH. UK.

Tel: +44(0)1675 466992

Email: info@sampling.com

Web: www.sampling.com

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Page 2 of 2

- *Le informazioni sopra ci sono state fornite da i nostri fornitori, vengono trasmesse in buona fede e in base alle nostre conoscenze.*

Español

- Confirmamos que las mercancías están fabricadas con poliestireno que se ajusta a la FDA CFR 177.1640
- La resina poliestireno utilizada en la fabricación de los productos anteriores está libre de BSE/TSE. Durante su fabricación, este elemento no entra en contacto con ninguno de los productos o procesos que puedan presentar un riesgo de BSE/TSE.
- Estas mercancías se moldean y envasan en una sala limpia de clase 100.000. Además se envasan individualmente.
- Este producto está diseñado para un solo uso. No debe utilizarse varias veces.
- La información detallada más arriba nos ha sido facilitada por nuestros proveedores, la transmitimos de buena fe y la consideramos correcta a nuestro mejor saber y entender.

Português

- *Confirmamos que os produtos são fabricados a partir de poliestireno que está em conformidade com FDA CFR 177.1640*
- *A poliestireno resina usada na fabricação dos produtos acima é BSE / TSE livre. Durante a fabricação deste item não entra em contacto com quaisquer produtos ou processos que podem representar um risco de BSE / TSE.*
- *Estes bens são moldados e embalados em uma sala limpa classe 100.000. Eles são embalados individualmente.*
- *Este produto é projetado para uma única utilização. Não deve ser usado várias vezes.*
- *A informação acima foi fornecida a nós pelos nossos fornecedores, a informação transmitida é boa fé e é o melhor do nosso correcto conhecimento.*

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



Sampling Systems Ltd.

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