


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

Certificate of Irradiation

Date Issued: 08-Aug-2022

MY01S12688211-1-1

This is to certify that Synergy Sterilisation Rawang (M) Sdn. Bhd., 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 9001 Quality Management System
 EN ISO 13485 Quality System - Medical Devices

NITRITEX (M) SDN BHD
 No 2 Jalan Jurunilai U1/20
 Seksyen U1 Hicom Glenmarie Ind Park
 Selangor
 40150 Shah Alam

Order Information

Account Number:	101178			
Synergy Health Sales Part Reference:	1055044			
Customer Reference Number:	SNB22/0244			
Product Description:	BIOCLEAN EMERALD ST NIT (BENS)			
Validation Reference:	R150045 Rev.2			
Quantity Received:	280			
Customer Minimum Specification kGy:	25.0			
Customer Maximum Specification kGy:	40.0			
Other Process Details:	PACKING : 200Pairs/Ctn			
	PRODUCT	LOT NO	BATCH NO	QTY
	CODE			
	BENS6.5	22-1297	N62207017	180
	BENS8.0	22-1298	N62207018	100

Irradiation Data

Date and Time of Irradiation:	07-Aug-2022 02:16
Reference Dose Range kGy:	31.3 - 31.7
Calculated Minimum Dose kGy:	27.7
Calculated Maximum Dose kGy:	38.2

Irradiation Release Authorised By Synergy Sterilisation Rawang (M) Sdn. Bhd, a STERIS Company

Processing Site: Lot 42 Jalan Industrial 2/1, Rawang Integrated Industrial Park, Rawang, 48000 Phone No: +60(0)3 6099 9600

Registered Office: 170-09-01, Livingston Tower, Jalan Argyll, 10050 George Town, Pulau Pinang, MALAYSIA

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