

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

Certificate of Irradiation

Date Issued: 30-Sep-2023

MY01S12762991-1-1

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
ISO 9001 Quality Management System
EN ISO 13485 Quality System - Medical Devices

NITRITE (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:	1099182			
Customer Reference Number:	SNB23/0210			
Product Description:	BIOCLEAN-D ST. KIT BDKM (S-BDKM)			
Validation Reference:	R150111 Rev.2			
Quantity Received:	440			
Customer Minimum Specification kGy:	25.0			
Customer Maximum Specification kGy:	38.0			
Other Process Details:	PACKING : 15Pieces/Ctn			
	PRODUCT CODE	LOT NO	BATCH NO	QTY
	S-BDKM-XL	23-1277	-	434
	S-BDKM-M	23-1274	-	5
	S-BDKM-M	23-1274-X	-	1

Irradiation Data

Date and Time of Irradiation:	29-Sep-2023 19:48
Reference Dose Range kGy:	31.3 - 31.5
Calculated Minimum Dose kGy:	28.6
Calculated Maximum Dose kGy:	37.9

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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