


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

Certificate of Irradiation

Date Issued: 23-Dec-2022

MY01S12717768-1-1

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:	1055041			
Customer Reference Number:	SNB22/0420			
Product Description:	Bioclean Maxima St. Latex (BLLS)			
Validation Reference:	R150067 Rev.2			
Quantity Received:	14			
Customer Minimum Specification kGy:	25.0			
Customer Maximum Specification kGy:	40.0			
Other Process Details:	PACKING : 100Pair/Ctn			
	PRODUCT	LOT NO	BATCH NO	QTY
	CODE			
	BLLS90	22-2283	L42211034	14

Irradiation Data

Date and Time of Irradiation:	23-Dec-2022 06:43
Reference Dose Range kGy:	30.4 - 30.4
Calculated Minimum Dose kGy:	26.6
Calculated Maximum Dose kGy:	36.7

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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