

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

## Certificate of Irradiation

Date Issued: 05-Dec-2019

MY01S12368176-1-1

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: | 1130611                                  |
| Customer Reference Number:           | SNB19/0420                               |
| Product Description:                 | St Nit Sleeve 26 Port 12" (GSL36NITPP26) |
| Validation Reference:                | R160077 Rev.1                            |
| Quantity Received:                   | 2                                        |
| Customer Minimum Specification kGy:  | 25.0                                     |
| Customer Maximum Specification kGy:  | 40.0                                     |
| Other Process Details:               | PACKING : 40Pieces/Ctn                   |
|                                      |                                          |
| PRODUCT CODE                         | LOT NO BATCH NO QTY                      |
| GSL36NITPP26                         | 19-3931 N411911050 2                     |

### Irradiation Data

|                               |                   |
|-------------------------------|-------------------|
| Date and Time of Irradiation: | 05-Dec-2019 07:54 |
| Reference Dose Range kGy:     | 32.4 - 32.4       |
| Calculated Minimum Dose kGy:  | 27.6              |
| Calculated Maximum Dose kGy:  | 36.2              |

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: Suite 18.01, 18th Floor, MWE Plaza, No. 8, Lebuhr Farquhar, 10200, Penang, MALAYSIA

VAT Number: 000878280704