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# Certificate of Irradiation

Date Issued: 20-Feb-2014

MY01S11115403-1-1

This is to certify that Synergy Sterilisation Rawang (M) Sdn. Bhd. has where appropriate delivered an irradiation process in accordance with:

EN ISO 11137-1:2006 Sterilisation of Health Care Products  
 EN ISO 9001:2008 Quality Management System  
 EN ISO 13485:2012 Quality System - Medical Devices

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

## Order Information

| Account Number:                      | 101178                                                                                                                                                                                                                                            |                     |           |                     |           |         |           |        |    |         |           |         |    |
|--------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|-----------|---------------------|-----------|---------|-----------|--------|----|---------|-----------|---------|----|
| Synergy Health Sales Part Reference: | 1055043                                                                                                                                                                                                                                           |                     |           |                     |           |         |           |        |    |         |           |         |    |
| Customer Reference Number:           | SNB14/0045                                                                                                                                                                                                                                        |                     |           |                     |           |         |           |        |    |         |           |         |    |
| Product Description:                 | Bioclean Extra 400 St Latex                                                                                                                                                                                                                       |                     |           |                     |           |         |           |        |    |         |           |         |    |
| Validation Reference:                | 0.0171                                                                                                                                                                                                                                            |                     |           |                     |           |         |           |        |    |         |           |         |    |
| Quantity Received:                   | 112                                                                                                                                                                                                                                               |                     |           |                     |           |         |           |        |    |         |           |         |    |
| Customer Minimum Specification kGy:  | 25.0                                                                                                                                                                                                                                              |                     |           |                     |           |         |           |        |    |         |           |         |    |
| Customer Maximum Specification kGy:  | 40.0                                                                                                                                                                                                                                              |                     |           |                     |           |         |           |        |    |         |           |         |    |
| Customer Unit Lot/Batch Number:      | SNB14/0045                                                                                                                                                                                                                                        |                     |           |                     |           |         |           |        |    |         |           |         |    |
| Other Process Details:               | Irradiation No: S1111540311<br>Description: Bioclean Extra 400 St Latex (BLAS)<br>Packing: 200 Pairs/ ctn                                                                                                                                         |                     |           |                     |           |         |           |        |    |         |           |         |    |
|                                      | <table><tr><th>Lot No</th><th>Batch No</th><th>Product Code / Size</th><th>Qty(ctns)</th></tr><tr><td>14-0247</td><td>L61402020</td><td>BLAS-L</td><td>72</td></tr><tr><td>14-0220</td><td>L61402016</td><td>BLAS-XL</td><td>40</td></tr></table> | Lot No              | Batch No  | Product Code / Size | Qty(ctns) | 14-0247 | L61402020 | BLAS-L | 72 | 14-0220 | L61402016 | BLAS-XL | 40 |
| Lot No                               | Batch No                                                                                                                                                                                                                                          | Product Code / Size | Qty(ctns) |                     |           |         |           |        |    |         |           |         |    |
| 14-0247                              | L61402020                                                                                                                                                                                                                                         | BLAS-L              | 72        |                     |           |         |           |        |    |         |           |         |    |
| 14-0220                              | L61402016                                                                                                                                                                                                                                         | BLAS-XL             | 40        |                     |           |         |           |        |    |         |           |         |    |
|                                      | Total : 112 Cartons                                                                                                                                                                                                                               |                     |           |                     |           |         |           |        |    |         |           |         |    |

## Irradiation Data

|                               |                   |
|-------------------------------|-------------------|
| Date and Time of Irradiation: | 20-Feb-2014 05:41 |
| Reference Dose Range kGy:     | 30.2 - 31.1       |
| Calculated Minimum Dose kGy:  | 25.0              |
| Calculated Maximum Dose kGy:  | 31.9              |



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Irradiation Release Authorised By Synergy Health plc