synergyhealth

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Certificate of Irradiation

Date Issued: 22-Feb-2014 MY01S11116011-1-1

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:	1055035
Customer Reference Number:	SNB14/0047
Product Description:	BIOCLEAN DISPOSABLE
Validation Reference:	0.0010
Quantity Received:	18
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	38.0
Customer Unit Lot/Batch Number:	SNB14/0047
Other Process Details:	Irradiation No: S1111601111 Description: Bioclean C Disp St Sleevecover (S-BCSC) Packing: 180 Pieces/ ctn

Lot No	Batch No	Product Code / Size	Qty(ctns)
14-0208	-	S-BCSC	18

Total : 18 Cartons

Irradiation Data

Date and Time of Irradiation:	22-Feb-2014 00:05
Reference Dose Range kGy:	30.1 - 30.1
Calculated Minimum Dose kGy:	27.4
Calculated Maximum Dose kGy:	31.2

Irradiation Release Authorised By Synergy Health plc