BioClean Maxima™

Product Information

Europe (Headquarters)

Nitritex Ltd
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www.BioClean.com

BioClean pure • product • protection

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BIOCLEAN MAXIMA™
Sterile Latex Gloves
BLLS

About

The 600mm (24") BioClean Maxima™ Sterile Latex Glove is specifically manufactured to provide shoulder length protection without sacrificing the exceptional flexibility and comfort provided by latex. The natural-coloured, hand specific, anatomically shaped glove features a textured surface for enhanced grip and a beaded cuff for stability on the arm.

Specifications

COMPATIBILITY:
ISO Class 4 & EU GMP Grade A

LENGTH:
600mm (24")

MATERIAL:
Latex

PROTEIN LEVEL:
Less than 50µg/gram

SURFACE:
Textured

SHAPE:
Hand specific

COLOUR:
Natural

STERILIZATION:
Gamma irradiation

Features

- Exceptional flexibility and comfort
- 600mm (24") providing shoulder length protection
- Powder-free
- Beaded cuff
- EasyOn™ proprietary technology allows for easy double-donning
- Non-particulating EasyTear™ packaging

CE 0120 EN 374 EN 374

Ms.G.Love™ represents BioClean's range of cleanroom gloves

Quality Standards

- Manufactured in a facility holding ISO 9001: 2008 and 89/686/EEC Article 11b certifications
- Conforms to Category 3 - Complex Design Personal Protective Equipment PPE Directive 89/686/EEC
- Processed in an NEBB certified ISO Class 4 environment
- Complies with the requirements of Glove Standard EN420:2003 and EN374-1, 2 & 3:2003
- Physical properties comply with European Medical Glove Standard EN455-2:2009
- Sterilized in accordance with ISO 11137-1:2006

Sterilization

Method: Gamma irradiation
Minimum Dose: 25kGy
Sterility Assurance Level: 10^{-6}

Shelf Life & Storage

Five (5) years from date of manufacture. Store in a dry, cool place (<40°C) away from direct sunlight and fluorescent light.

Physical Properties

CHARACTERISTICS	VALUE	TEST METHOD
Freedom From Holes	1.5 AQL Performance Level 2	EN 374-2:2003
Minimum Length (mm/inches)	580/22.8	EN 420:2003
Single Wall Thickness Minimum (mm)	Cuff: 0.12 Palm: 0.18 Finger Tip: 0.20	EN 455-2:2009
Force At Break During Shelf Life	≥12 N	EN 455-2:2009

PALM WIDTHS (mm) ± 5mm								
SIZE	6.0*	6.5	7.0	7.5	8.0	8.5	9.0	10.0*
mm	77	83	89	95	102	108	115	120
TEST METHOD					EN455-2:2009			

Glove Cleanliness Characteristics

PARTICLES					TYPICAL PARTICLE COUNT		TEST METHOD
≥ 0.5µm(counts/cm^2)					<1200		IEST-RP-CC005.3
TYPICAL EXTRACTABLE IONS							TEST METHOD
ANIONS	Fluoride	Chloride	Nitrite	Bromide	Nitrate	Phosphate	Sulphate	IEST-RP-CC005.3
(µg/cm^2)	ND	0.12	0.01	ND	0.01	ND	0.01	
CATIONS	Lithium	Sodium	Ammonium	Potassium	Calcium	Magnesium	Zinc	
(µg/cm^2)	ND	0.01	NT	0.03	0.07	0.02	ND	
ND = Not Detected, NT = Not Tested								

TO ORDER

Re-order code	Size
BLLS60	6.0*
BLLS65	6.5
BLLS70	7.0
BLLS75	7.5
BLLS80	8.0
BLLS85	8.5
BLLS90	9.0
BLLS100	10.0*

Packing

One pair per inner PE wallet; one wallet per sealed EasyTear™ PE pouch; 10 pouches per sealed outer PE bag; 10 outer bags per lined carton (100 pairs).

*Size subject to minimum order quantity and lead time.

CONTACT

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Other Regions

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Nitritex Beyond Critical Supplies

BioClean™ is a brand of Nitritex Ltd.
For more information, please visit www.bioclean.com

BLLS/1610/PDS27

FC-BIOS Sdn Bhd (188200-H)
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Excellence in Safety Life Science, Clinical, Environment and Process Supplies

Date : 27 February 2001

Dear Sir

REF : SAMPLE ID : BLLS - Product Code : LSCT 600S
Lot No. : 0J 11 05
TEST DATE : 26 February 2001

1/ **EXTRACTION METHOD :**

a) Aseptically turning the glove sample outside in and filling each glove with 40ml water for Injection (WFI) and removing all visible air bubbles within the glove.

b) Each pair of glove was clamped 1.5cm from the cuff to seal the WFI within the glove.

c) 10 pairs of gloves were similarly treated and extracted at temperature of 37°C for 60 minutes as per EN 455-3.

d) A pooled sample of 10ml (0.5ml per piece of glove) was used for testing after centrifuging at 2,000g for 5 minutes.

2/ **EXTRACT pH DETERMINATION WITH pH Meter :**

pH of reaction Mix (Sample + LAL)	=	7.35
pH of Sample	=	4.93
pH of Sample after pH adjustment	=	7.44

3/ **METHODOLOGY**

a) Gel Clot Assay Methodology adhering to the EP Supplement 1999 : 2.6.14 Bacterial Endotoxin was employed.

...2/-

...2/-

b) Test Parameters

Endotoxin Limit per pair of gloves	:	20EU
WFI Extract volume per pair of gloves	:	80ml
Endotoxin Limit of Extract	:	0.25EU/mL

4/ **RESULTS :**

Endotoxin Concentration per ml of Pooled Extract	=	4 x 0.03 EU/mL
	=	0.12 EU/mL
Endotoxin Concentration per pair of glove	=	0.12 EU/mL x 80mL
	=	9.6 EU

Full test report printout attached.

Regards

Lim You Seng
Product Manager

SAMPLE TEST RAW DATA REPORT

TEST DATE: 26 February 2001

LYSATE LOT#: 500-04-150

ENDOTOXIN LOT#: 77

SENSITIVITY (λ): 0.03 EU/mL

POTENCY (EU/ng): 10

LRW LOT#: 314-1452

Procedure: Gel-clot method with product positive control(s) spiked at 2λ.

Sample Identification:

BLLS - Product Code : LSCT 600S

Size : 8 Total : 15 pairs Lot No. : 0J 11 05

Score

Standard Series:

Replicate	2λ	λ	0.5λ	0.25λ	-ve ctrl
1	+	+	-	-	-
2	+	+	-	-	-

Assay Test

Sample	1:1	1:2	1:4	1:8	1:16	1:32	1:64
Unspiked							
1.	-	-	+	-	-	-	-
2.	-	-	+	-	-	-	-
Spiked							
1.	-	-	+	+	+	+	+
2.	-	-	+	+	+	+	+

pH of reaction Mix (Sample + LAL) = 7.35

pH of Sample = 4.93

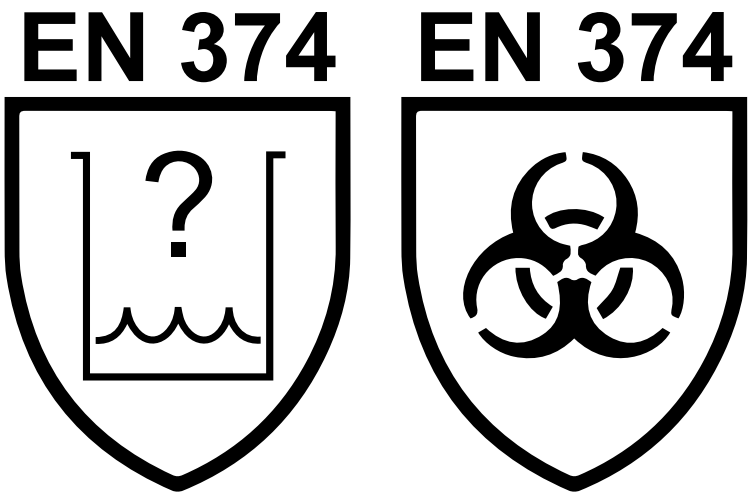
pH of Sample after pH adjustment = 7.44

(* note: EP Guideline - pH of reaction mixture should be 6.0 – 7.5; sample pH should not be < 6.5)

European Standard EN 374-3:2003
Protective gloves against chemicals and micro-organisms

Part 3: Determination of resistance to permeation by chemicals
Permeation time in minutes

Tested Chemical	Breakthrough Time	Permeation Performance Level
Formaldehyde 30%	>480	6
Hydrochloric acid 32%	448	5
Sodium hypochlorite 12%	>480	6



Standard	EN374-2:2003
Acceptance Quality Limit (AQL)	1.5
Performance Level	2

PRÜFSTELLE TEXTIL

SÄCHSISCHES TEXTIL FORSCHUNGS INSTITUT e.V.

Durch das DAP Deutsches Akkreditierungssystem Prüfwesen - vertreten im Deutschen Akkreditierungsrat - akkreditiertes Prüflaboratorium Die Akkreditierung gilt für die in der Urkunde aufgeführten Prüfverfahren.

DAP-PL-1167.99

Durch die Zentralstelle der Länder für Sicherheitstechnik (ZLS) akkreditierte Prüfstelle für Produkte im Sinne der EG-Richtlinie für Persönliche Schutzausrüstungen 89/686/EWG und des §9 Abs. 2 Gerätesicherheitsgesetz

ZLS-P-566/05

Von der Federation Internationale de L'Automobile (FIA) Paris zugelassene Stelle zur Prüfung von Schutzkleidung für Auto-Rennfahrer - FIA standard 8856-2000

UNTERSUCHUNGSBERICHT I TESTREPORT

Order no. STFI:	**2340/09**	
Order no. applicant:	1st delivery	4832 of 19/11/2009
	2nd delivery	4906 of 11/02/2010
	3rd delivery	4971 of 14/04/2010
Report date:	5 May 2010	
Testing officer:	Fritzsche	

Applicant:

Nitritex Ltd.
Mr. Roland Sore/Mr. Philip Wan
Minton Enterprise Park
Oaks Drive, Newmarket
Suffolk CB8 7YY
United Kingdom

Testing application:

of:	1st delivery	20/30 November 2009 (E-mail)
	2nd delivery	11 February 2010 (E-mail)
	3rd delivery	15 April 2010 (E-mail)
order receipt on:	20/30 November 2009	
	11 February 2010	
	15 April 2010	
sample receipt on:	1st delivery	24 November 2009
	2nd delivery	16 February 2010
	3rd delivery	19 April 2010

Test specimen: 5-Fingers-Gloves
(palm and back of gloves with pattern; cuff without pattern)

Marking by applicant:				Coding for handling of order:
BioClean Maxima™ STERILE POWDER-FREE CLEANROOM GLOVES REF: BLLS; 600 mm (24") Length				
Delivery	LOT NO:	BATCH NO:	Size(s):	
1st:				Sample 01
	094/08	0851L01	6.5	
	062/08	0847L01	7.0	
	094/08	0848L03	7.5	
	062/08	0840L03	8.0	
	062/08	0842L29	8.5	
	287/07	0902L04	9.0	
2nd:				Sample 01/1
	094/08	0851L01	6.5	
	094/08	0848L03	7.5	
	062/08	0840L03	8.0	
	062/08	0842L29	8.5	
	287/07	0902L04	9.0	
3rd:	191/09	L41001038	7.5	Sample 01/2
	234/09	L40912001	7.5	Sample 01/3

Sampling was carried out by applicant. In the testing department are no knowledge's about method of sampling

Test content:

Selected tests of gloves as delivered as ordered by applicant:

Test property	Test method [1)]
Material	
pH value	EN 420:2003/EN 1413:1998; tested according to EN ISO 3071:2006 (EN 1413:1998 withdrawn and replaced with EN ISO 3071:2006)
Resistance against permeation by chemicals	EN 374-3:2003, test chemicals see test data
Gloves	
Resistance against penetration/ Air-Leak-Test Water-Leak-Test	EN 374-2:2003 4.1/5.2; air pressure 3,0 kPa 4.2/5.3

1) Tests were carried out according to German standards which correspond to international standards.

Test results:

Test property/ Material	Dimension	Test data/ Sample 01 (as delivered)
pH value		5,7
Resistance against permeation by chemicals/Breakthrough time	min	
Formaldehyde 30 %		> 480
Hydrochloric acid 32 %		465 / 450 / 430
Sodium hypochlorite 12 %		> 480

Test property/ Gloves	Test data/ Sample 01 (as delivered)	
Resistance against penetration/ Air-Leak-Test	sizes 6.5 / 7.0 / 8.0 / 8.5 / 9.0	tight [2]
	size 7.5	leak [3]
Water-Leak-Test		[4]

Test property/ Gloves	Test data/ Sample 01/1 (as delivered)	
Resistance against penetration/ Air-Leak-Test	sizes 6.5 / 8.0 / 8.5 / 9.0	tight [2]
	size 7.5 (both gloves)	leak

Test property/ Gloves	Test data/ Sample 01/2 (as delivered)	Sample 01/3 (as delivered)
Resistance against penetration/ Air-Leak-Test	size 7.5 tight [2]	size 7.5 tight [2]

2) only conditionally testable because gloves are ballooned unevenly during test (cuff area more than area of palm and back of glove)
3) one leak in cuff observed
4) not applicable (caused of a very high stretching of gloves during test)

The test results refer to the delivered samples.
This Test Report should not be published in parts.

Dr. Matthias Mägel
Head of the testing department

stfi geprüft

Dipl.-Ing. Sibylle Fritzsche
Responsible testing officer

DOSE MAPPING REPORT
NITRITEX (M) SDN BHD
FOR

BIOCLEAN MAXIMA ST. LATEX (BLLS)

Validation Report Number : R150067 Rev 1

Summary of Performance Qualification:

Customer Name: **Nitritex (M) Sdn Bhd**
Report Ref.: **R150067**
Issue Date: **15.06.2015** Expiry Date: **15.06.2020**

Product Description: **Bioclean Maxima St. Latex (BLLS)**

Type of package: **Corrugated Carton**

Carton dimension : **315mm (L) x 270mm (W) x 290mm (H) (18 ctns / tote)**

Method : **ASTM E 2303-03**

Reference Standard : **ISO 11137-1:2006**

Dose Specification:

Minimum dose (kGy): 25.0
Maximum dose (kGy): 40.0

Requirement	Minimum specification	Maximum specification
Dose at DRef	28.6	33.1
Dwell time(s)	402	457
Number of Xs	41	47
Correction Factor	0.8741	1.2085

Conclusion

The delivered dose in the product presentation illustrated on page 7 achieves the requested dose specification of 25.0 kGy minimum dose and 40.0 kGy maximum dose. In order to meet this specification during routine processing the recorded dose at Dref must be between **28.6** kGy and **33.1** kGy. This incorporates an estimation of uncertainty associated with the measurement system.

Authorisation

Position	Signature	Date
Sr. Executive QA		14/09/2015
QA Manager		14/09/2015

Note:
It is the responsibility of the customer to routinely provide product in the presentation and orientation outlined in this report.
This performance qualification validates the delivery of radiation doses only. Validation of the sterilisation effect and radiation induced material effects, if any, are not addressed by this qualification.

Qualification data is obtained by placing 4034 **NE** Red dosimeters in a defined pattern throughout a Synergy Sterilisation tote loaded with product

The performance qualification is conducted in triplicate with the dosimeters placed throughout the product to assess both the dose distribution and determine the variability of the absorbed dose measurements, when processed under the same processing conditions.

Following processing the relationship between $\overline{D_{ref}} / \overline{D_{min}}$ and $\overline{D_{ref}} / \overline{D_{max}}$ are calculated to determine an acceptable D_{Ref} processing range.

D_{Ref} processing range is calculated by multiplying the R_{min} by the Customer minimum specification and the R_{max} by the Customer maximum specification. During routine processing if the D_{Ref} value falls within this range then processing is deemed as meeting the required specification:

D_{Ref} Minimum = Expected value of R_{min} x Minimum Dose Required
D_{Ref} Maximum = Expected value of R_{max} x Maximum Dose Required

Uncertainty

The specification for D_{Ref} incorporates an estimation of the uncertainty associated with the measurement system. Uncertainty has been calculated using the method outlined in ASTM E 2303-03. This method provides a confidence level of 95%.

Definitions

D_{Ref} - Reference Dose
D_{Min} - Minimum Dose
D_{Max} - Maximum Dose
R_{min} - D_{Ref}/D_{Min} ratio
R_{max} - D_{Ref}/D_{Max} ratio
CV% - Coefficient of Variance
Co60 - Cobalt 60

Product: Bioclean Maxima St. Latex (BLLS) - Low Density

Analysis for the Calculation of Release Specification Incorporating Uncertainties

Position	PQ1	PQ2	PQ3	Mean	Stdev	CV	Sum of Squared Differences
A11	28.3	28.6	29.1	28.7	0.40	1.39	0.33
A21	**29.9**	**30.8**	**30.3**	**30.3**	**0.45**	**1.49**	**0.41**
A31	29.8	30.1	29.8	29.9	0.17	0.57	0.06
A41	**29.5**	**29.8**	**29.8**	**29.7**	**0.17**	**0.57**	**0.06**
A51	28.0	28.3	27.5	27.9	0.40	1.43	0.33
A15	**31.1**	**31.0**	**31.9**	**31.3**	**0.49**	**1.57**	**0.49**
A25	31.6	31.7	31.5	31.6	0.10	0.32	0.02
A35	**31.7**	**31.7**	**31.9**	**31.8**	**0.12**	**0.38**	**0.03**
A45	31.8	31.9	31.3	31.7	0.32	1.01	0.21
A55	**30.9**	**30.5**	**30.7**	**30.7**	**0.20**	**0.65**	**0.08**
A19	34.2	34.0	34.1	34.1	0.10	0.29	0.02
A29	**34.4**	34.4	**34.0**	**34.3**	**0.23**	**0.67**	**0.11**
A39	33.9	**34.6**	**34.4**	**34.3**	0.36	1.05	0.26
A49	**34.3**	**34.1**	**33.9**	**34.1**	**0.20**	**0.59**	**0.08**
A59	33.3	33.3	33.1	33.2	0.12	0.36	0.03
B11	**25.8**	**25.0**	**25.2**	**25.3**	**0.42**	**1.66**	**0.35**
B21	26.5	26.0	26.5	26.3	0.29	1.10	0.17
B31	**25.2**	**25.3**	**25.4**	**25.3**	**0.10**	**0.40**	**0.02**
B41	25.2	25.9	26.0	25.7	0.44	1.71	0.38
B51	**25.0**	**25.1**	**25.3**	**25.1**	**0.15**	**0.60**	**0.05**
B15	26.0	25.6	25.8	25.8	0.20	0.78	0.08
B25	**26.0**	**26.3**	**26.0**	**26.1**	**0.17**	**0.65**	**0.06**
B35	25.1	26.2	25.9	25.7	0.57	2.22	0.65
B45	**25.0**	**26.5**	**26.1**	**25.9**	**0.78**	**3.01**	**1.21**
B55	25.7	25.7	25.4	25.6	0.17	0.66	0.06
B19	**29.6**	**29.6**	**29.5**	**29.6**	**0.06**	**0.20**	**0.01**
B29	29.9	30.1	30.1	30.0	0.12	0.40	0.03
B39	**29.4**	**30.0**	**30.1**	**29.8**	**0.38**	**1.28**	**0.29**
B49	29.8	30.2	30.0	30.0	0.20	0.67	0.08
B59	29.6	29.6	29.6	29.6	0.00	0.00	0.00

Pooled variance (s^2overall) **0.10**
Minimum detectable difference (δ) **0.43**
Mean Minimum dose (DMin) **25.1 (B 51)**
Mean Maximum dose (DMax) **34.3 (A 29 & A 39)**

SS Rawang Ratio:	
1/Rmin	**0.874**
1/Rmax	**1.195**

Expected value of Rmin (Dref/Dmin) **1.144** *
Expected value of Rmax (Dref/Dmax) **0.837** *
Remarks: * incorporates an estimation of the uncertainty
Customer Spec Min **25.0** Max **40.0**

Dref Minimum **28.6**
Dref Maximum **33.5**

Product: Bioclean Maxima St. Latex (BLLS) - High Density

Analysis for the Calculation of Release Specification Incorporating Uncertainties

Position	PQ1	PQ2	PQ3	Mean	Stdev	CV	Sum of Squared Differences
A11	28.7	29.2	28.2	28.7	0.50	1.74	0.50
A21	29.8	29.5	30.4	29.9	0.46	1.54	0.42
A31	29.6	30.3	29.8	29.9	0.36	1.20	0.26
A41	28.5	29.5	28.3	28.8	0.64	2.22	0.83
A51	27.7	28.1	27.6	27.8	0.26	0.94	0.14
A15	30.8	30.5	30.6	30.6	0.15	0.49	0.05
A25	30.8	30.7	31.1	30.9	0.21	0.68	0.09
A35	31.6	31.6	31.6	31.6	0.00	0.00	0.00
A45	30.9	30.9	31.1	31.0	0.12	0.39	0.03
A55	30.0	30.5	30.1	30.2	0.26	0.86	0.14
A19	33.1	33.6	33.1	33.3	0.29	0.87	0.17
A29	33.9	33.8	33.5	33.7	0.21	0.62	0.09
A39	35.0	35.2	33.8	34.7	0.76	2.19	1.15
A49	33.7	34.9	33.0	33.9	0.96	2.83	1.85
A59	33.4	33.3	32.6	33.1	0.44	1.33	0.38
B11	25.5	25.7	26.0	25.7	0.25	0.97	0.13
B21	26.7	26.4	26.8	26.6	0.21	0.79	0.09
B31	25.6	25.6	25.4	25.5	0.12	0.47	0.03
B41	26.0	26.0	25.4	25.8	0.35	1.36	0.24
B51	25.2	25.3	25.1	25.2	0.10	0.40	0.02
B15	26.3	25.9	26.0	26.1	0.21	0.80	0.09
B25	26.5	26.6	26.1	26.4	0.26	0.98	0.14
B35	25.9	26.7	25.4	26.0	0.66	2.54	0.86
B45	26.4	26.7	25.0	26.0	0.91	3.50	1.65
B55	26.0	25.9	25.6	25.8	0.21	0.81	0.09
B19	29.7	30.0	29.7	29.8	0.17	0.57	0.06
B29	30.9	30.2	29.7	30.3	0.60	1.98	0.73
B39	30.8	30.0	29.2	30.0	0.80	2.67	1.28
B49	30.3	30.2	29.7	30.1	0.32	1.06	0.21
B59	30.1	29.7	29.4	29.7	0.35	1.18	0.25

Pooled variance (s^2overall) **0.20**
Minimum detectable difference (δ) **0.61**
Mean Minimum dose (DMin) **25.2 (B 51)**
Mean Maximum dose (DMax) **34.7 (A 39)**

SS Rawang Ratio:	
1/Rmin	**0.878**
1/Rmax	**1.209**

Expected value of Rmin (Dref/Dmin) **1.139** *
Expected value of Rmax (Dref/Dmax) **0.827** *
Remarks: * incorporates an estimation of the uncertainty
Customer Spec Min **25.0** Max **40.0**

Dref Minimum **28.5**
Dref Maximum **33.1**

synergyhealth

Product Detail

Customer Name: **Nitritex (M) Sdn Bhd**
A/C No: **101178** Report Ref.: **150067**
Issue Date: **15.06.2015** Expiry Date: **15.06.2020**

Product Description: **Bioclean Maxima St. Latex (BLLS) - Low Density**

Density : **0.259 g/cm3 (Size 6.5) &0.271 g/cm3 (Size 7.0) &0.272 g/cm3 (Size 7.5)**
Plant Batch No: **S11406989-1-1**
Current Cobalt Loading (Mc_i): **1,704,688**
Standard Plant Dwell Time (sec): **402** Dwell Time (sec): **402**
Number of Xs: **41.00** Value of X: **9.81**
Dose Range Specification (kGy): **25.0** Min. **40.0** Max.

Minimum dwell time to achieve	Minimum dose	Maximum dose
First tote	**402**	467
Second tote	402	**465**
Third tote	399	467

Product Description: **Bioclean Maxima St. Latex (BLLS)- High Density**

Density : **0.274 g/cm3 (Size 8.0) & 0.297 g/cm3 (Size 9.0)**
Plant Batch No: **S11406989-1-1**
Current Cobalt Loading (Mc_i): **1,704,688**
Standard Plant Dwell Time (sec): **402** Dwell Time (sec): **402**
Number of Xs: **41.00** Value of X: **9.81**
Dose Range Specification (kGy): **25.0** Min. **40.0** Max.

Minimum dwell time to achieve	Minimum dose	Maximum dose
First tote	399	459
Second tote	397	**457**
Third tote	**402**	476

Customer Name: **Nitritex (M) Sdn Bhd**

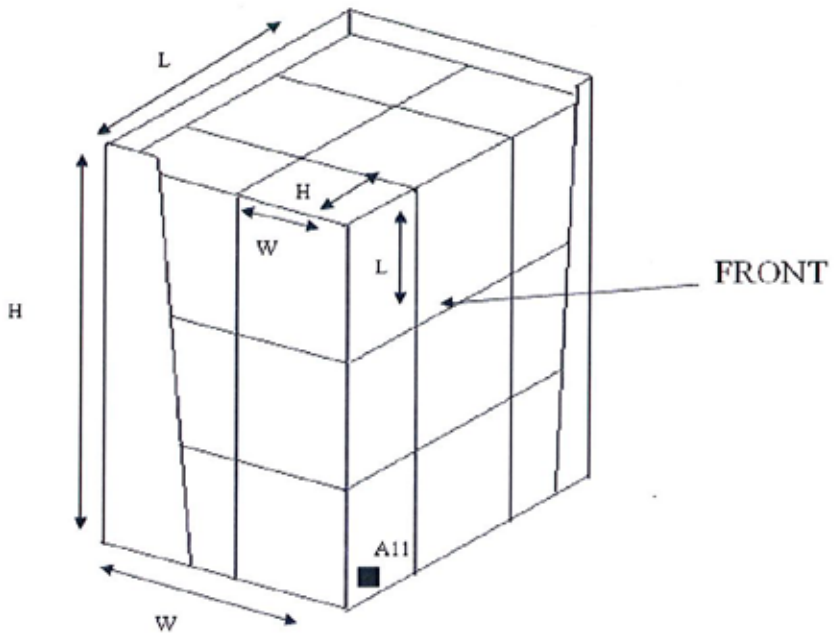
Type of Package: **Corrugated Cartons**

Product Description: **Bioclean Maxima St. Latex (BLLS)**

Issue Date: **15.06.2015**
Expiry Date: **15.06.2020**

This performance qualification relates only to the above product loaded in the configuration outlined below.

Carton dimension = 315mm (L) x 270mm (W) x 290mm (H) (18 ctns / tote)



Remark : A11 is the routine process monitoring

Authorised By:	Signature	Date
QA Manager		14/07/2015

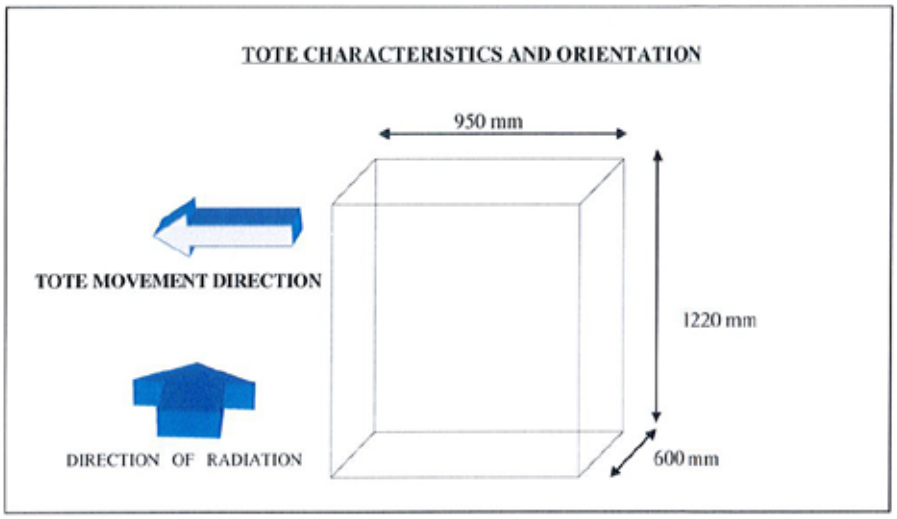
Customer Name: **Nitritex (M) Sdn Bhd**

Type of Package: **Corrugated Cartons**

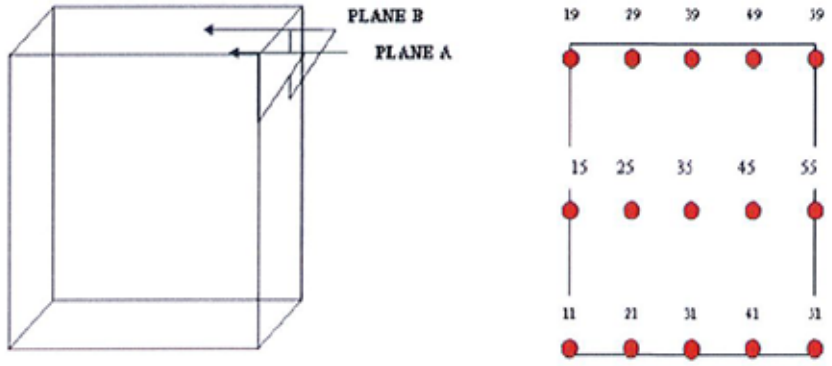
Product Description: **Bioclean Maxima St. Latex (BLLS)**

Issue Date: **15.06.2015**
Expiry Date: **15.06.2020**

This performance qualification relates only to the above product loaded in the configuration outlined below.



LOCATION OF DOSIMETERS



Authorised By:	Signature	Date
QA Manager		14/07/2015

Declaration of Conformity

Nitritex Ltd

Minton Enterprise Park
Oaks Drive
Newmarket
Suffolk
CB8 7YY

declares that the new PPE described hereafter

	Product Code
BioClean Maxima Gloves	BLLS

is in conformity with the provisions of Council Directive 89/686/EEC and, where such is the case, with the National Standard transposing standards EN 420+A1: 2009, EN 374-1: 2003 and EN 374-2: 2003

Is identical to the PPE which is subject to EC Certificate of Conformity
No 044/2015/0549
issued by CENTEXBEL, Belgium, Notified Body Number 0493

is subject to the procedure set out in Article 11 point B of directive 89/686/EEC under the supervision of approved body, SGS UK Ltd, Notified Body Number 0120

Done at: Newmarket

Derek Watts
Managing Director

28/05/2015
Dated

Iss 03

synergyhealth
our work protects your world

www.synergyhealthplc.com

Certificate of Irradiation

Date Issued: 09-Mar-2016

MY01S11578117-1-1

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

EN ISO 11137-1:2015 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:	1055041
Customer Reference Number:	SNB16/0029
Product Description:	Bioclean Maxima St. Latex (BLLS)
Validation Reference:	R150067 Rev.1
Quantity Received:	94
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Other Process Details:	PACKING : 100 PAIRS/CTN

PRODUCT CODE	LOT NO	BATCH NO	QTY
BLLS-75	15-3027	L41511013	58
BLLS-80	16-0540	L41602021	36

Irradiation Data

Date and Time of Irradiation:	09-Mar-2016 07:02
Reference Dose Range kGy:	29.9 - 30.5
Calculated Minimum Dose kGy:	26.1
Calculated Maximum Dose kGy:	36.9

Irradiation Release Authorised By Synergy Health plc

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, Lebuh Farquhar, 10200 , Penang , MALAYSIA
VAT Number: 000878280704

Certificate GB10/81851

The management system of

Nitritex Ltd.

Minton Enterprise Park, Oaks Drive,
Newmarket, Suffolk, CB8 7YY, UK

has been assessed and certified as meeting the requirements of

ISO 9001:2008

For the following activities

Manufacture and supply of sterile and non-sterile latex, nitrile, vinyl, co-polymer blend, polyisoprene and neoprene gloves for surgical, patient examination, cleanroom application and chemical protection. Supply of surgical facemasks. Supply of Cleanroom and protective garments. Supply of Cleanroom consumables and accessories.

Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2008 requirements may be obtained by consulting the organisation

This certificate is valid from 14 October 2014 until 14 October 2017
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 14 October 2017
Issue 5. Certified since 18 October 2010

Authorised by

SGS United Kingdom Ltd Systems & Services Certification
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

SGS 9001-8 01 0614

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UKAS MANAGEMENT SYSTEMS
0005

Certificate GB04/61092

The management system of

Nitritex Ltd.

Minton Enterprise Park, Oaks Drive,
Newmarket, Suffolk, CB8 7YY, UK

has been assessed and certified as meeting the requirements of

ISO 13485:2003
EN ISO 13485:2012

For the following activities

Manufacture and supply of sterile and non-sterile latex, nitrile, vinyl, co-polymer blend, polyisoprene and neoprene gloves for surgical, patient examination. Supply of surgical facemasks.

This certificate is valid from 02 February 2015 until 14 October 2017
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 14 October 2017
Issue 11. Certified since 09 February 2004

Authorised by

SGS United Kingdom Ltd Systems & Services Certification
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

SGS 13485-2 0714

UKAS MANAGEMENT SYSTEMS
0005

QMS International plc

ISO 14001 REGISTERED

This document certifies that the environmental management systems of

NITRITEX LIMITED

Minton Enterprise Park, Oaks Drive, Newmarket, Suffolk CB8 7YY

have been assessed and approved by QMS International plc to the following environmental management systems, standards and guidelines:-

ISO 14001 : 2004

The approved environmental management systems apply to the following:-

SUPPLIERS OF SPECIALIST PROTECTION PRODUCTS FOR CLEAN ROOM, MEDICAL AND INDUSTRIAL APPLICATIONS.

Original Approval: 01 March 2004

Current Certificate: 29 January 2015

Certificate Expiry: 28 February 2024

Certificate Number: 14122589

On behalf of QMS International plc

ASCB Accreditation Services Worldwide

This Certificate remains valid while the holder maintains their management system in accordance with the published ISO standard. To check the validity and status of this certificate please visit www.IRQAO.com or email status@qmsplc.com

This Certificate is the property of QMS International plc and must be returned in the event of cancellation.

QMS International plc | Muspole Court | Muspole Street | Norwich | NR3 1DJ | United Kingdom
(+44) 01603 630345 www.qmsuk.com

NEXTECH

NE BB

CERTIFICATE OF COMPLIANCE

NITRITEX (M) SDN. BHD.

Packing Room 1 - ISO Class 4	*Packing Room 2 - ISO Class 5*
Clean Corridor 1 - ISO Class 4	*Changing Room - ISO Class 6*
Clean Corridor 2 - ISO Class 5	*Cartoning Room - ISO Class 7*

Test Condition: At Rest

As per requirement of ISO 14644 the designated area listed have met the respective acceptance criteria. Testing was performed as outlined in the above standard and the results are attested to it in the
Report No.: **036/CR~02/2017**

Nextech Sdn Bhd
NE BB
TAN CHEE KIAN
CERTIFICATION
3144
Exp: 31/03/18
Cleanroom Performance Testing

Date of Certification : 23/02/2017
Due Date : 23/02/2018

Alvin Tan Chee Kian
CPT Certified Professional

NEXTECH SDN. BHD.
19, Jalan Bukit Badung 26/4, HICOM Industrial Estate
40000 Shah Alam, Selangor Darul Ehsan, Malaysia.
Tel: 03-51923833 Fax : 03-51922088

Certificate MY08/75286

The management system of

Nitritex (M) Sdn. Bhd.

No. 2, Jalan Jurunilai U1/20, Section U1
Hicom Glenmarie Industrial Park
40150 Shah Alam, Selangor
MALAYSIA

has been assessed and certified as meeting the requirements of

ISO 9001:2008

For the following activities

Manufacture and supply of sterile and non-sterile latex, nitrile, vinyl, co-polymer blend, polyisoprene and neoprene gloves for surgical, patient examination, cleanroom application and chemical protection. Processing and packing of sterile and non-sterile cleanroom consumables.
Manufacture and supply of cleanroom reusable garments.

Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2008 requirements may be obtained by consulting the organisation

This certificate is valid from 23 July 2016 until 14 September 2018 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 14 August 2018
Issue 7. Certified since 24 July 2008

Authorised by

SGS United Kingdom Ltd Certification and Business Enhancement
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

SGS 9001-8 01 0216

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Certificate MY08/75285

The management system of

Nitritex (M) Sdn. Bhd.

No. 2, Jalan Jurunilai U1/20, Section U1
Hicom Glenmarie Industrial Park
40150 Shah Alam, Selangor
MALAYSIA

has been assessed and certified as meeting the requirements of

ISO 13485:2003
EN ISO 13485:2012

For the following activities

Manufacture and Supply of Sterile and Non-Sterile Latex, Nitrile, Vinyl, Co-Polymer Blend, Polyisoprene and Neoprene Gloves for Surgical, Patient Examination and Cleanroom Application. Processing and Packing of Sterile and Non-Sterile Cleanroom Consumables.

This certificate is valid from 23 July 2016 until 31 March 2019 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 31 March 2019
Issue 5. Certified since 24 July 2008

Authorised by

UKAS MANAGEMENT SYSTEMS
0005

SGS United Kingdom Ltd Systems & Services Certification
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

SGS 13485 2 1114

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EC Certificate Production Quality Assurance System: Certificate MY08/75284

The management system of

Nitritex (M) Sdn. Bhd.

No. 2, Jalan Jurunilai U1/20, Section U1
Hicom Glenmarie Industrial Park
40150 Shah Alam, Selangor
MALAYSIA

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

For the following products

MDD, Annex V
Sterile Latex, Nitrile, Polyisoprene, Neoprene and Co-Polymer Blend Surgical Gloves.
MDD Annex V (Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions)
Sterile Latex, Nitrile, Polyisoprene, Neoprene and Co-Polymer Blend Examination Gloves.

For placing on the market of Class IIb or Class III devices covered by this certificate, an EC Type Examination Certificate according to Annex III is required.

This certificate is valid from 23 July 2016 until 23 July 2021 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 23 May 2019
Issue 6. Certified since 24 July 2008

Certification is based on reports numbered MY/KUL MY01700

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 13 0311

Certificate MY08/75287

The management system of

Nitritex (M) Sdn. Bhd.

No. 2, Jalan Jurunilai U1/20, Section U1
Hicom Glenmarie Industrial Park
40150 Shah Alam, Selangor
MALAYSIA

has been assessed and certified as meeting the requirements of

Directive 89/686/EEC

Article 11B

For the following activities

Manufacture of Sterile & Non Sterile Latex, Nitrile and Co-Polymer Blend Gloves for Chemical Protection.
Manufacture of Disposable Protective Garments.
Note: "All products marked CE0120 must have a valid EC Type Examination Certificate issued under Article 10."

This certificate is valid from 23 July 2016 until 23 July 2019 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 23 May 2019
Issue 5. Certified since 24 July 2008

Authorised by

SGS United Kingdom, Notified Body 0120
United 202B World Parkway, Weston-super-mare, BS22 6WA, UK
t +44 (0) 1934 522917 f +44(0) 1934 522137 www.sgs.com

SGS CE 11B 1215

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