BioClean Permaflow™

Product Information

Europe (Headquarters)

Nitritex Ltd
Minton Enterprise Park
Oaks Drive, Newmarket
Suffolk, CB8 7YY
United Kingdom

T: +44 1638 663338
F: +44 1638 668890
E: europe@bioclean.com

Americas

Nitritex Canada Ltd
7030 Woodbine Avenue
Suite 500, Markham
Ontario, L3R 6G2
Canada

T: +1 905 946 9539
F: +1 905 946 8584
E: americas@bioclean.com

Asia & Middle East

Nitritex (M) Sdn Bhd
2 Jalan Jurunilai U1/20
Seksyen U1, Hicom Glenmarie
Industrial Park, 40150 Shah Alam
Selangor, Malaysia

T: +60 3 5569 3857/3859
F: +60 3 5569 3862
E: malaysia@bioclean.com

www.BioClean.com

BioClean™ pure • product • protection

BIOCLEAN™ PERMAFLOW™

Irradiated Cleanroom Ballpoint Pen

S-BPBP-1

About

BioClean Permaflow™ Cleanroom Pens with fade and water resistant permanent ink. With alcohol-resistant labeling for easy cleaning within a critical environment, they are ISO Class 4 & EU GMP Grade A compatible. Available in a range of colours.

Specifications

MATERIAL:
Polypropylene barrel and lid with permanent ink

LENGTH:
140mm (5.5")

COMPATIBILITY:
ISO Class 4 & EU GMP Grade A

COLOUR:
Black, Blue or Red ink

STERILIZATION:
Gamma irradiation

Features

- Alcohol resistant labelling
- Processed to ensure ISO Class 4 & EU GMP Grade A compatibility
- Permanent ink Black, Blue or Red
- Fade and water resistant
- Quick drying
- Non-toxic

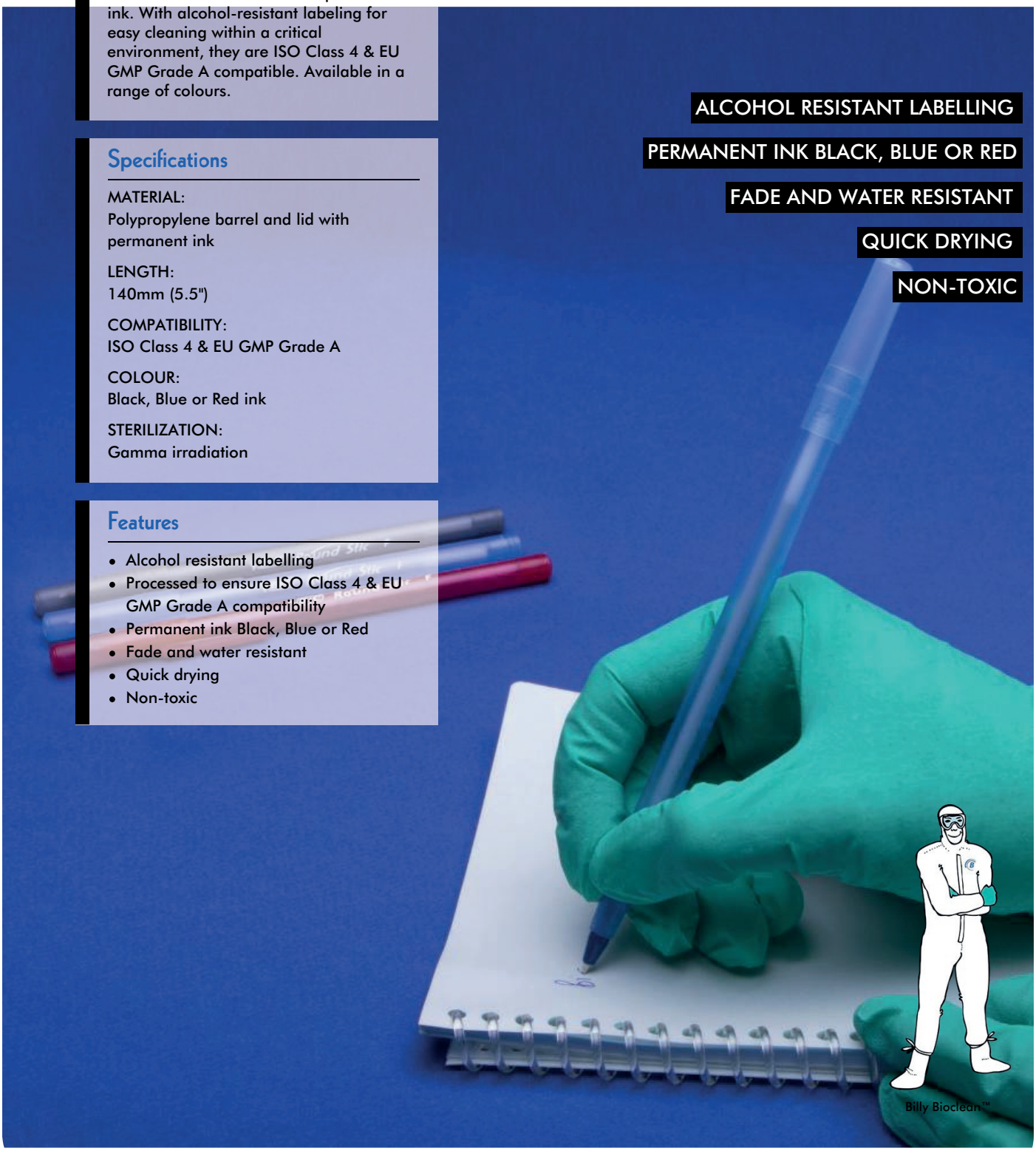
ALCOHOL RESISTANT LABELLING

PERMANENT INK BLACK, BLUE OR RED

FADE AND WATER RESISTANT

QUICK DRYING

NON-TOXIC



Quality Standards

- Processed in a facility holding the ISO 9001:2008 certification
- Processed in a NEBB certified ISO Class 4 cleanroom environment

Sterilization

Method: Gamma irradiation
Minimum Dose: 25kGy

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.

TO ORDER

Re-order code	Size
S-BPBP-1-BK	Black
S-BPBP-1-BL	Blue
S-BPBP-1-RD	Red

Packing

One pen per inner PE bag; Three pens per sealed outer PE bag; 100 outer PE bags per carton liner; One carton liner per carton (300 pens).

CONTACT

Europe

(Headquarters)

Nitritex Ltd.
Minton Enterprise Park,
Oaks Drive,
Newmarket, Suffolk,
CB8 7YY,
United Kingdom
T: +44 (0) 1638 663338
F: +44 (0) 1638 668890
E: europe@bioclean.com

Other Regions

Asia:
malaysia@bioclean.com
Americas:
americas@bioclean.com

Nitritex Beyond Critical Supplies

GB10/81851 GB04/61092

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

S-BPBP-1/1610/PDS4

BIOCLEAN™ PERMAFLOW™

Sterile Cleanroom Pen

S-BPFP

About

BioClean Permaflow™ Cleanroom Pens are sterile with fade and water resistant super permanent ink. With alcohol-resistant labeling for easy cleaning within a critical environment, they are ISO Class 4 & EU GMP Grade A compatible. Available in a range of colours.

Specifications

MATERIAL:
Plastic with super permanent ink

LENGTH:
140mm (5.5")

COMPATIBILITY:
ISO Class 4 & EU GMP Grade A

CONSTRUCTION:
Plastic construction with super permanent ink.

COLOUR:
Black, Blue or Red ink

STERILIZATION:
Gamma irradiation

Features

- Autoseal ink prevents drying
- Alcohol resistant labelling
- Processed to ensure ISO Class 4 & EU GMP Grade A compatibility
- Super permanent ink Black, Blue or Red
- Fade and water resistant
- Quick drying
- Non-toxic

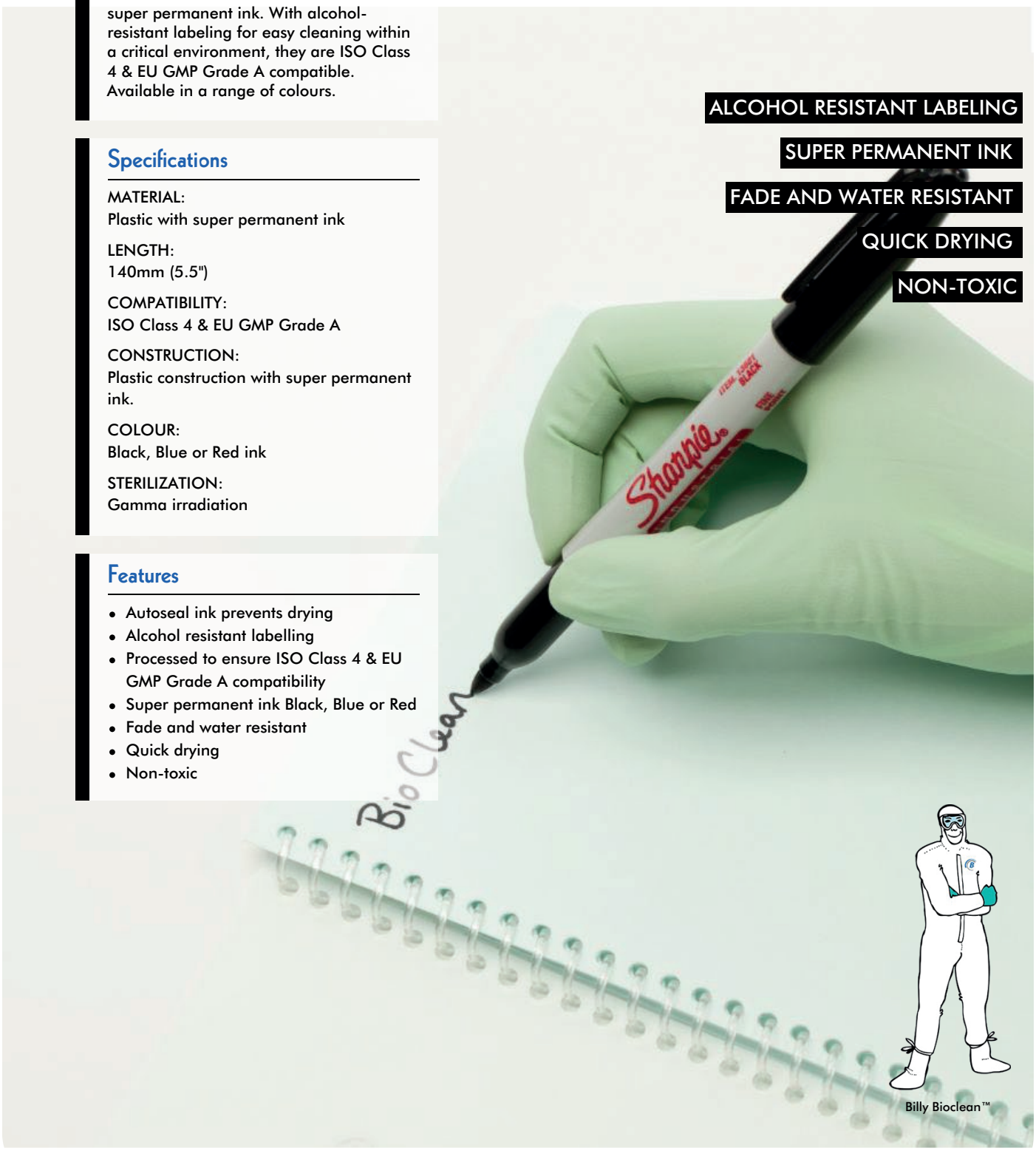
ALCOHOL RESISTANT LABELING

SUPER PERMANENT INK

FADE AND WATER RESISTANT

QUICK DRYING

NON-TOXIC



Billy Bioclean™

Quality Standards

- Manufactured in a facility holding the ISO 9001:2008 certification
- Processed in an NEBB certified ISO Class 4 cleanroom environment

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.

TO ORDER

Re-order code	Size
S-BPFP-BK1	Black
S-BPFP-BL1	Blue
S-BPFP-RD1	Red

Packing

One pen per sealed inner PE bag; 10 inner bags per sealed outer PE bag; 20 outer bags per lined carton (200 pens)

CONTACT

Europe

(Headquarters)

Nitritex Ltd.
Minton Enterprise Park,
Oaks Drive,
Newmarket, Suffolk,
CB8 7YY,
United Kingdom
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americas@bioclean.com

Nitritex Beyond Critical Supplies

GB10/81851

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

S-BPFP/1606/PDS12

S-BPFP

Material Safety Data Sheet

Product Identification

Product Name:	**BioClean Permaflow**
Product Description:	Sterile Cleanroom Marker Pen
Product Code:	S-BPFP

Composition / Information on Ingredients:

Ingredient	Symbol	CAS No	Purpose
Ethylene glycol monobutyl ether	$C_6H_{14}O_2$	11-76-2	Dye
Ethylene glycol monobutyl ether	$C_6H_{14}O_2$	110-80-5	Dye
Ethyl alcohol	C_2H_6O	64-17-5	Liquid medium

All chemicals are non-toxic/non-hazardous

Hazards Identification

BioClean Permaflow cleanroom marker pens are non-toxic/non-hazardous.

First Aid Measures

None under normal use conditions

Fire Fighting Measures

Not applicable

Accidental Release Measures

Not applicable

Handling and Storage

No special handling required

Exposure Controls and Personal Protection

Not applicable

Physical and Chemical Properties

Stable

Stability and Reactivity

Stable

Material Safety Data Sheet

Toxological Information

BioClean Permaflow cleanroom marker pens are non-toxic/non-hazardous and considered safe under normal conditions

Ecological Information

There are no ecological implications associated with the use of BioClean Permaflow

Disposal Considerations

Disposal in accordance with local regulations

Transport Considerations

No special transport considerations. Non-hazardous cargo.

Regulatory Information

None

Other Information

None

Contact Details:

United Kingdom	Canada	Malaysia	China
NITRITEX LTD Minton Enterprise Park, Oaks Drive, Newmarket, Suffolk, CB8 7YY United Kingdom Tel: +44 (0) 1638 663338 Fax: +44 (0) 1638 668890 Email: info@nitritex.com	NITRITEX CANADA LTD 7030 Woodbine Avenue, Suite 500, Markham, Ontario L3R 6G2 Canada Tel: +1 (905) 946 9539 Fax:+1 (905) 946 8584 Email: info@nitritexcanada.com	NITRITEX MALAYSIA SDN BHD No.2, Jalan Jurnilai U1/20, Seksyen U1, Hicom Glenmarie Industrial Park, 40150 Shah Alam, Selangor, Malaysia Tel:+603 (5569) 3857 Fax:+603 (5569) 3862 Email: info@nitritex.com.my	NITRITEX CHINA Room 304, Sunny Plaza Jing'an, No. 351 Anyuan Road, Shanghai 200040, PR China Tel:+86-21-5252 0157 Fax:+86-21-6266 0431 Email: info@nitritex.cn

DOSE MAPPING REPORT
NITRITEX (M) SDN BHD

FOR
BIOCLEAN P/FLOW ST CR MARKER
(S-BPFP)

Validation Report Number : R150125 Rev 1

Summary of Performance Qualification:

Customer Name: **Nitritex (M) Sdn Bhd**
Report Ref.: **R150125 Rev 1**
Issue Date: **22.08.2015** Expiry Date: **22.08.2020**

Product Description: **Bioclean P/Flow St. Cr Marker (S-BPFP)**

Type of package: **Corrugated Carton**

Carton dimension : **305 mm (L) x 300 mm (W) x 205 mm (H) (30 ctns/tote)**

Method : **ASTM E 2303-03**

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

Dose Specification:

Minimum dose (kGy): 25.0
Maximum dose (kGy): 38.0

Requirement	Minimum specification	Maximum specification
Dose at DRef	27.4	31.6
Dwell time(s)	372	421
Number of Xs	37	42
Correction Factor	0.9124	1.2025

Conclusion

The delivered dose in the product presentation illustrated on page 6 achieves the requested dose specification of 25.0 kGy minimum dose and 38.0 kGy maximum dose. In order to meet this specification during routine processing the recorded dose at Dref must be between **27.4** kGy and **31.6** kGy. This incorporates an estimation of uncertainty associated with the measurement system.

Authorisation

Position	Signature	Date
Sr. Executive QA	Nini	28/08/2015
QA Manager		28/08/2015

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.

Product description: **Bioclean P/Flow St. Cr Marker (S-BPFP)**

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 P/Flow St. Cr Marker (S-BPFP)

Analysis for the Calculation of Release Specification Incorporating Uncertainties

Position	PQ1	PQ2	PQ3	Mean	Stdev	CV	Sum of Squared Differences
A11	30.6	30.3	30.9	30.6	0.30	0.98	0.18
A21	**32.6**	**32.2**	**32.5**	**32.4**	**0.21**	**0.65**	**0.09**
A31	33.0	32.1	32.8	32.6	0.47	1.44	0.45
A41	**32.2**	**31.7**	**32.1**	**32.0**	**0.26**	**0.81**	**0.14**
A51	30.0	30.2	30.1	30.1	0.10	0.33	0.02
A15	**34.1**	**34.0**	**34.5**	**34.2**	**0.26**	**0.76**	**0.14**
A25	35.0	34.7	35.1	34.9	0.21	0.60	0.09
A35	**34.7**	**34.3**	**34.9**	**34.6**	**0.31**	**0.90**	**0.19**
A45	33.9	34.6	35.0	34.5	0.56	1.62	0.62
A55	**33.5**	**33.4**	**34.6**	**33.8**	**0.67**	**1.98**	**0.89**
A19	35.4	35.6	36.0	35.7	0.31	0.87	0.19
A29	**36.9**	**36.7**	36.4	**36.7**	**0.25**	**0.68**	**0.13**
A39	**37.1**	36.4	**37.0**	**36.8**	0.38	1.03	0.29
A49	**35.8**	**36.4**	**36.8**	**36.3**	**0.50**	**1.38**	**0.51**
A59	34.8	35.3	35.6	35.2	0.40	1.14	0.33
B11	**28.2**	**27.6**	**28.0**	**27.9**	**0.31**	**1.11**	**0.19**
B21	29.1	29.0	28.8	29.0	0.15	0.52	0.05
B31	**28.5**	**28.4**	**28.7**	**28.5**	**0.15**	**0.53**	**0.05**
B41	29.2	29.1	29.4	29.2	0.15	0.51	0.05
B51	**28.6**	**28.2**	**28.5**	**28.4**	**0.21**	**0.74**	**0.09**
B15	30.2	30.3	31.3	30.6	0.61	1.99	0.74
B25	**31.3**	**30.9**	**30.9**	**31.0**	**0.23**	**0.74**	**0.11**
B35	31.1	30.1	31.2	30.8	0.61	1.98	0.74
B45	**31.0**	**30.5**	**31.1**	**30.9**	**0.32**	**1.04**	**0.21**
B55	30.8	30.2	31.0	30.7	0.42	1.37	0.35
B19	**32.1**	**31.1**	**32.1**	**31.8**	**0.58**	**1.82**	**0.67**
B29	32.4	31.7	32.2	32.1	0.36	1.12	0.26
B39	**32.5**	**32.2**	**32.1**	**32.3**	**0.21**	**0.65**	**0.09**
B49	32.6	31.9	32.8	32.4	0.47	1.45	0.45
B59	32.3	31.3	31.9	31.8	0.50	1.57	0.51

Pooled variance (s^2overall) **0.15**
Minimum detectable difference (б) **0.53**
Mean Minimum dose (DMin) **27.9 (B 11)**
Mean Maximum dose (DMax) **36.8 (A 39)**

SS Rawang Ratio:	
1/Rmin	**0.912**
1/Rmax	**1.203**

Expected value of Rmin (Dref/Dmin) **1.097** *
Expected value of Rmax (Dref/Dmax) **0.831** *
Remarks: * incorporates an estimation of the uncertainty
Customer Spec Min **25.0** Max **38.0**

Dref Minimum **27.4**
Dref Maximum **31.6**

Product Detail

Customer Name: **Nitritex (M) Sdn Bhd**
A/C No: **101178** Report Ref.: **150125**
Issue Date: **22.08.2015** Expiry Date: **22.08.2020**

Product Description: **Bioclean P/Flow St. Cr Marker (S-BPFP)**

Density : **0.147 g/cm3**
Plant Batch No: **S11452315-1-1**
Current Cobalt Loading (Mc_i): **1,667,665**
Standard Plant Dwell Time (sec): **411** Dwell Time (sec): **411**
Number of Xs: **41.00** Value of X: **10.03**
Dose Range Specification (kGy): **25.0** Min. **38.0** Max.

Minimum dwell time to achieve	Minimum dose	Maximum dose
First tote	364	**421**
Second tote	**372**	426
Third tote	367	422

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

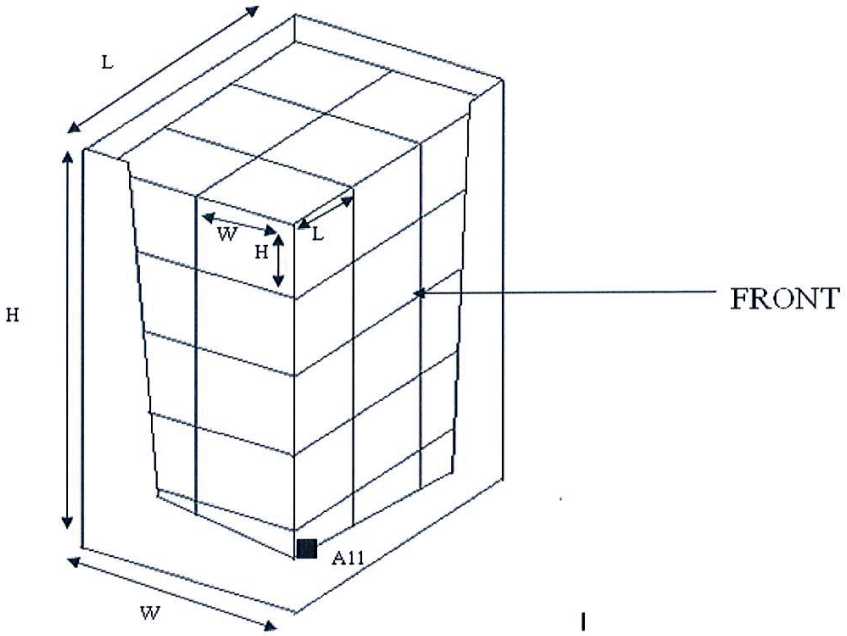
Type of Package: **Corrugated Carton**

Product Description: **Bioclean P/Flow St. Cr Marker (S-BPFP)**

Issue Date: **22.08.2015**
Expiry Date: **22.08.2020**

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

Carton dimension = 305 mm (L) x 300 mm (W) x 205 mm (H) (30 ctns/tote)



Remark : A11 is the routine process monitoring

Authorised By:	Signature	Date
QA Manager		28/08/2015

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

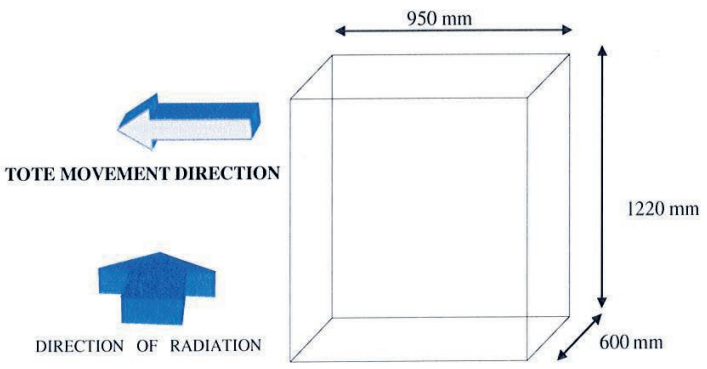
Type of Package: **Corrugated Carton**

Product Description: **Bioclean P/Flow St. Cr Marker (S-BPFP)**

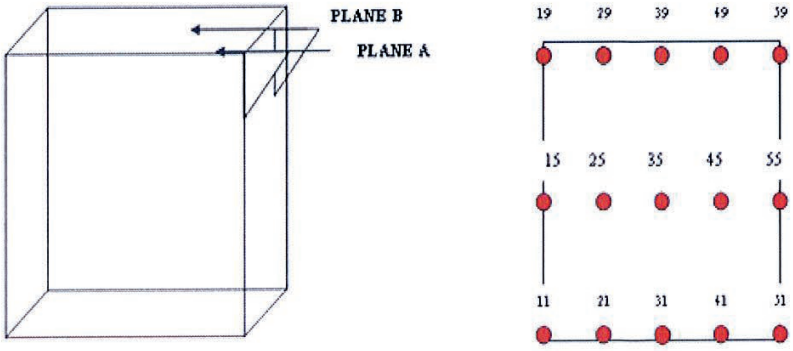
Issue Date: **22.08.2015**
Expiry Date: **22.08.2020**

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

TOTE CHARACTERISTICS AND ORIENTATION



LOCATION OF DOSIMETERS



Authorised By:	Signature	Date
QA Manager		28/08/2015

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

Supply of sterile and nonsterile latex, nitrile, vinyl, co-polymer blend, polyisoprene and neoprene gloves for surgical, patient examination, cleanroom application and chemical protection, gauntlets, mittens and sleeves for use on Restricted Access Barrier Systems (RABS), Isolators and Glove Boxes. Supply of surgical facemasks. Manufacture and 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 24 April 2017 until 14 October 2017
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 14 October 2017
Issue 6. Certified since 18 October 2010

Authorised by

SGS United Kingdom Ltd
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

Page 1 of 1

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

NEBB

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
NEBB
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