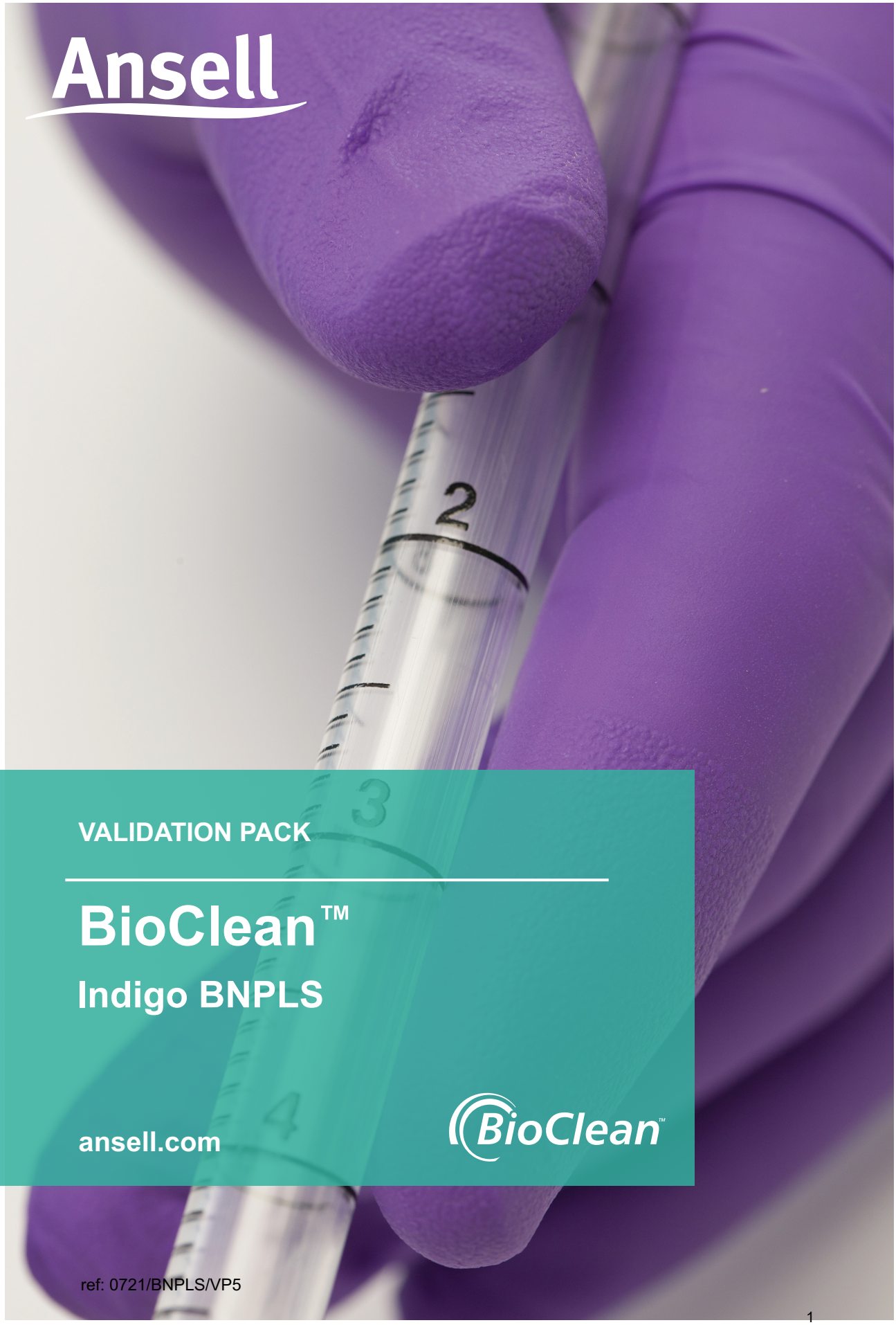

Ansell

VALIDATION PACK

BioClean™

Indigo BNPLS

ansell.com

BioClean™

ref: 0721/BNPLS/VP5

TABLE OF CONTENTS

BioClean™

Indigo BNPLS

Sterile Nitrile Cleanroom Glove

NBR
Nitrile

Indigo nitrile glove, offering chemical splash protection and excellent tactility when handling small apparatus

BioClean Indigo Sterile Nitrile Cleanroom Gloves feature textured fingers for enhanced grip and are latex-free to eliminate Type I allergies. Processed to ensure ISO Class 4 & EU GMP Grade A compatibility, BioClean Indigo gloves are also resistant to a wide range of chemicals.

Please contact Ansell Customer Service for specific chemotherapy drug permeation times and recommendations.

- Resistant to a wide range of chemicals
- Powder-free & latex-free
- Textured fingers for enhanced grip
- Excellent antistatic properties
- Non-particulating EasyTear packaging

Industries

- Controlled and Critical Environments
- Production and Manufacturing

WWW.ANSELL.COM

Ansell

BioClean™

Indigo BNPLS

Sterile Nitrile Cleanroom Glove

TECHNICAL DATA SHEET

PRODUCT INFORMATION

	Indigo BNPLS
Material	Nitrile
Color	Purple
Shape	Ambidextrous
Cuff	Beaded
Manufacturing/QMS Audit Standards	Manufacturing QMS Audit Standards ISO 9001, PPE Regulation 2016 425 Module D
Regulatory/Standards Compliance	ASTM D6978, CE 0598, EN 420:2003 + A1:2009, EN 420:2003 + A1:2009, EN 421:2010, EN 455 Part 2, EN ISO 374-1:2016, EN ISO 374-5:2016, Food Contact, Category III
Storage	Store in a dry, cool place (<40°C) away from direct sunlight and fluorescent light.
Country of Origin	Malaysia
Available sizes	5-5.5, 6-6.5, 7-7.5, 8-8.5, 9.0, 10
Powder Content	Powder-Free
External Glove Surface	Textured Fingers and Palm
Internal Glove Surface	Chlorinated
Sterilization Method	GAMMA irradiation (25 kGy)
Sterilization Minimum Dose	25kGy
Sterility Assurance Level	10^{-6}
Cleanroom Class	Class 10/ISO 4 & EU GMP Grade A
Shelf Life	Five (5) years from date of manufacture.
Tested for use with Chemotherapy Drugs	Yes
Protein Level	N/A: contains no natural rubber latex

GLOBAL PRODUCT DATASHEET

BioClean™

Indigo BNPLS

Sterile Nitrile Cleanroom Glove

PHYSICAL PROPERTIES

	Typical Values						Testing Method
Sizes	10	5-5.5	6-6.5	7-7.5	8-8.5	9	EN 420
Length (mm/in)	300 / 12						
Palm Width (mm/in)	119/4.7	75/2.9	83/3.3	95/3.7	106/4.2	114/4.5	
Freedom from Holes	0.65 AQL Performance Level 3						EN 374-2
Typical Particle Count ≥0.5µm (counts / cm^2)	<3500 ≥ 0.5µm(counts/cm2						IEST-RP-CC005.4
Minimum Single Wall Palm Thickness (mm/mil)	:0.13 / 5.12						EN 455-2
Minimum Single Wall Finger Thickness (mm/mil)	0.20 / 7.87						EN 455-2
Minimum Single Wall Cuff Thickness (mm/mil)	0.10 / 3.94						EN 455-2
	During Ageing						
Force at Break (N)	≥9 N						EN 455-2

IONIC CONTENT

Concentration in µg/cm^2	Typical	Concentration in µg/cm^2	Typical
Ammonium	0.038	Nitrate	1.553
Bromide	0.0147	Nitrite	Not Detected
Calcium	0.585	Phosphate	Not Detected
Chloride	0.187	Potassium	0.217
Fluoride	Not Detected	Sodium	0.095
Lithium	Not Detected	Sulphate	0.206
Magnesium	Not Detected	Zinc	Not Detected

ORDERING INFORMATION

	SIZE	10	5-5.5	6-6.5	7-7.5	8-8.5	9
Indigo BNPLS	REORDER NO.	BNPLS1010	BNPLS5055	BNPLS6065	BNPLS7075	BNPLS8085	BNPLS9090

Performance Standards and Regulatory Compliance

CE 0598 EN 421 EN ISO 374-1/Type C EN ISO 374-5 VIRUS

For additional information visit us at www.ansell.com, or call us at

Europe, Middle East & Africa Region
Ansell Healthcare Europe NV
T: +32 (0) 2 528 74 00
F: +32 (0) 2 528 74 01

Asia Pacific Region
Ansell Global Trading Center
T: +603 8310 6688
F: +603 8310 6699

North America Region
Ansell Healthcare Products LLC
US T: +1 800 800 0444
US F: +1 800 800 0445
CA T: +1-800-363-8340

Latin America & Caribbean Region
Ansell Commercial Mexico S.A. de C.V.
T: +52 442 248 1544 / 248 3133

Australia
Ansell Limited
T: +61 1800 337 041
F: +61 1800 803 578

UK
Ansell Nitritex
T: +44 1638 663338
F: +44 1638 668890

Ansell

EU DECLARATION OF CONFORMITY

The Manufacturer
NITRITEX (M) SDN BHD,
NO.2, JALAN JURUNILAI U1/20,
SEKSYEN U1, HICOM GLENMARIE
INDUSTRIAL PARK,
40150 SHAH ALAM,
SELANGOR, MALAYSIA

and authorized representative:
NITRITEX LTD
UNIT 4, MINTON ENTERPRISE PARK
OAKS DRIVE, NEWMARKET
SUFFOLK, CB8 7YY, UK

declare under their sole responsibility, that the PPE described hereafter:

BioClean Indigo BNPLS

Products manufactured as of: [18/10/2018] and till: [18/10/2023]

PPE to be used against category III risks

is in conformity with the provisions of Regulation (EU) 2016/425 and with the European harmonized standards EN 420:2003 + A1:2009, EN 421:2010, EN ISO 374-1:2016, EN ISO 374-5:2016 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 060/2018/1829, issued by the Notified Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

and is subject to the procedure set out in Annex VIII (Module D) of the Regulation under the supervision of the Notified Body:

SGS FIMKO OY (0598)
TAKOMOTIE 8,
FI-00380 HELSINKI,
FINLAND

Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 18/10/2018

EU TYPE CERTIFICATE

In application of the Regulation (EU) 2016/425 of 9 March 2016 concerning the harmonization of the Member States legislation relative to personal protective equipment, Centexbel Notified body 0493 authorized by the FPS Economy (Federal Public Services) has issued the following:

EU TYPE EXAMINATION CERTIFICATE

Nr. 060/2018/1829

This EU Type examination certificate is valid until 18 Oct 2023

to: **Nitritex (M) Sdn Bhd, Shah Alam, Selangor**

for: **BioClean Indigo BNPLS Sterile Nitrile Gloves**

The personal protective equipment above mentioned satisfies the applicable essential safety requirements of the Regulation (EU) 2016/425.

For the argumentation, the following standards are used:

EN 420:2003+A1:2009	Protective gloves - General requirements and test methods
EN 421:2010	Protective gloves against ionizing radiation and radioactive contamination
EN ISO 374-1:2016	Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks
EN ISO 374-5:2016	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risk

If there is a former EC Type examination certificate according to the Directive 89/686/EEC this certificate remains valid until 21 April 2023 unless it expires before that date, for products that were manufactured before the issuance of this new EU Type examination certificate according to the Regulation (EU) 2016/425.

This is PPE of category III, subject to regular checks in accordance with article 19 of the European PPE Regulation. In agreement with the manufacturer's choice audits of the production process shall be carried out to assess the Conformity of type (Module D). The manufacturer must be able, on request, to present the audit report. A first audit shall be performed at the latest on 31 Dec 2019 and at least be repeated with intervals of one year.

This declaration applies to the equipment as submitted in the type testing and described in the manufacturer's technical documentation (As described in 2016/425 Annex III) that is registered with number 11132.

Issued by Centexbel, Notified Body 0493, in Ghent, on 18 Oct 2018

Inge De Witte
Certification Manager

Attached: 1 Annex

ANNEX

EU TYPE EXAMINATION CERTIFICATE Nr. 060/2018/1829

1. Applicant

Nitritex (M) Sdn Bhd
No 2 Jalan Jurunilai U1/20, Seksyen U1
Hicom Glenmarie Industrial Park
40150 Shah Alam, Selangor
Malaysia

2. Description

EN 421:2010

EN ISO 374-1 / Type C

EN ISO 374-5

VIRUS

3. Materials and accessories

Gloves

- Nitritex Nitrile Gloves - File 11132

4. Technical documentation

Summary test results

EN 420:2003+A1:2009 Gloves **Nitritex Nitrile Gloves - File 11132**

Method	Description	Result	Class
EN 1413	pH - textile	PASS	
EN 14362-1	AZO dyes for colored gloves	PASS	
EN 420 length	Length	PASS	
EN 420 dexterity	Dexterity	PASS	Level 5
1149-1 / 1149-2 / 1149-3	Electrostatic properties	PASS	

EN 421:2010 Gloves **Nitritex Nitrile Gloves - File 11132**

Method	Description	Result	Class
EN 420 dexterity	Dexterity	PASS	Level 5
EN 374-3	Permeation K	PASS	Level 6
EN 374-3	Permeation T	PASS	Level 6
EN 374-2	Penetration	PASS	
EN 388	Mechanical requirements	Dexterity is the most important parameter	
EN 421 4.3 method 5.1	Attenuation efficiency and uniformaty of distribution	/	/

EN ISO 374-1:2016 Gloves **Nitritex Nitrile Gloves - File 11132**

Method	Description	Result	Class
EN 374-2	Penetration	PASS	
EN 16523-1	Permeation K	PASS	Level 6
EN 16523-1	Permeation T	PASS	Level 6
EN 374-4	Degradation K	PASS	
EN 374-4	Degradation T	PASS	
Type of glove		PASS	Type C

EN ISO 374-5:2016 Gloves **Nitritex Nitrile Gloves - File 11132**

Method	Description	Result	Class
EN 374-2	Penetration	PASS	
ISO 16604 Proc. B	Protection against viruses	PASS	

Description/Picture of article

Article **BioClean Indigo BNPLS Sterile Nitrile Gloves**

The above picture is a general picture of the article. Possible variations of the above article can be present in the technical file.

Note :
Any modification in material, design, or other technical features must be brought to the attention of the Notified Body.

CERTIFICATE OF IRRADIATION

8497822

STERIS

http://www.steris-ast.com

Certificate of Irradiation

Date Issued: 06-Feb-2020 MY01S12393663-1-1

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:	1096999
Customer Reference Number:	SNB20/0038
Product Description:	BIOCLEAN INDIGO ST NIT (BNPLS)
Validation Reference:	R150083 Rev.1
Quantity Received:	39
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Other Process Details:	PACKING : 200Pairs/Ctn

PRODUCT CODE	LOT NO	BATCH NO	QTY
BNPLS7075	20-0064	N52001025	33
BNPLS1010	20-0173	N52001044	5
BNPLS1010	20-0173-X	N52001044	1

Irradiation Data

Date and Time of Irradiation:	06-Feb-2020 07:41
Reference Dose Range kGy:	30.8 - 31.8
Calculated Minimum Dose kGy:	26.8
Calculated Maximum Dose kGy:	37.1

Processing Site: Lot 42 Jalan Industrial 2/1, Rawang Integrated Industrial Park, Rawang, 48000 Phone No: +60(0)3 6099 9600

Registered Office: 170-09-01, Livingston Tower, Jalan Argyll, 10050 George Town, Pulau Pinang , MALAYSIA
VAT Number: 000878280704

CERTIFICATE OF IRRADIATION

8497822

STERIS

http://www.steris-ast.com

Certificate of Irradiation

Date Issued: 06-Feb-2020 MY01S12393663-1-1

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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

Irradiation Release Authorised By Synergy Sterilisation Rawang (M) Sdn. Bhd, a STERIS Company

CERTIFICATE OF CONFORMANCE

BioClean™
pure • product • protection

COC
BNPLS
BioClean Indigo

Certificate of Conformity

Size/Type	10.0
Lot No.	20-0173
Manufacture Date	01/2020
Expiry Date	12/2024
Sterilisation	COI Number: S1239366311
Certificate of Analysis result	Pass

Declaration of Conformity

The above product is hereby declared as conforming to;

- all technical product specifications
- all manufacturing control specifications
- all applicable standards and regulations specified
- all processing requirements as reported on the Certificate of Irradiation / Processing
- all test parameter ranges as reported on the Certificate of Analysis
- REACH Compliance
- EMEA/410/01 Compliance – as it is declared that this product is free from any animal derived materials (TSE/BSE) and materials derived from genetically modified organisms (GMO)

Issue

This Certificate of Conformity is issued by the authorised signatories on behalf of the authorised supplier.

Verified by:

Zana

QA Officer

Current product datasheets and Certificates of Irradiaton may be downloaded from the BioClean website, www.bioclean.com

Sales & Distribution
UK/EMEA
Nitritex Limited,
Minton Enterprise Park,
Newmarket, Suffolk,
CB8 7YY,
United Kingdom
Phone number:
+44(0) 1638 663338
europe@bioclean.com

Manufacturer, Sales & Distribution
APAC
Nitritex (M) Sdn Bhd, No.2,
Jalan Jurunilai U1/20, Seksyen U1,
Hicom Glenmarie Industrial Park,
40150 Shah Alam, Selangor,
Malaysia
Phone number:
+603 5569 3857/3859
malaysia@bioclean.com

Sales & Distribution
US
Ansell Healthcare Products LLC,
111 Wood Avenue South,
Suite 210, Iselin,
NJ 08830,
USA
Phone number:
1-800-800-0444
americas@bioclean.com

CERTIFICATE OF ANALYSIS

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COA
BNPLS
BioClean Indigo

Certificate of Analysis

Size/Type	10.0
Lot No.	20-0173
Batch No.	N52001044
Sterilization	THESE PRODUCTS ARE SUPPLIED STERILE
Expiry Date	12/2024

Test Data - Sampling Plan

Standard	Plan	AQL	Title	Sample Size	No. of Defects	QC Result
EN ISO 374-2	G-1	0.65	Water-tight Test	200	0	Pass
N/A	G-1	2.5	Visual Inspection - major	32	0	Pass
N/A	G-1	4.0	Visual Inspection - minor	32	0	Pass
EN 420	S-2	4.0	Dimensions	3	0	Pass
EN 455-2	S-2	4.0	Physical Properties	3	0	Pass
N/A	N/A	N/A	Packing conformity check	1	0	Pass
EN 455-2	N/A	≥9N	Force at Break during shelf life	13	N/A	Pass
IEST-RP-CC005.4	N=3	N/A	Extractable Ionic Burden	3	0	Pass
IEST-RP-CC005.4	N=3	N/A	Liquid Particle Count	3	0	Pass

Analysis Conclusion

This Certificate is based on the evaluation of samples of the above mentioned product and confirms that the product conforms to the specification requirements published by Nitritex Ltd.

This Certificate of Analysis is issued by the authorised signatory below.

Verified by:

Zana

QA Officer

Current product datasheets and Certificates of Irradiation may be downloaded from the BioClean website, www.bioclean.com

Sales & Distribution
UK/EMEA
Nitritex Limited,
Minton Enterprise Park,
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Phone number:
+44(0) 1638 663338
europe@bioclean.com

Manufacturer, Sales & Distribution
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Malaysia
Phone number:
+603 5569 3857/3859
malaysia@bioclean.com

Sales & Distribution
US
Ansell Healthcare Products LLC,
111 Wood Avenue South,
Suite 210, Iselin,
NJ 08830,
USA
Phone number:
1-800-800-0444
americas@bioclean.com

CHEMICAL PERMEATION SUMMARY

Ansell

BioClean™

BioClean™ Indigo Sterile Nitrile Gloves - BNPLS

CYTOSTATIC CHEMICAL PERMEATION REPORT

Permeation breakthrough times according to tests using standard ASTM D 6978 "Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs"

CHEMICAL AGENT	CAS NUMBER	MEAN BREAKTHROUGH TIME (MINUTES)	PROTECTION INDEX
Carmustine	154-93-8	3.3 mg/ml	1.7
Cisplatin	15663-27-1	1 mg/ml	>480
Cyclophosphamide	50-18-0	20 mg/ml	>480
Doxorubicin Hydrochloride	23214-92-8	2 mg/ml	>480
Etoposide	33419-42-0	20 mg/ml	>480
Fluorouracil	51-21-8	50 mg/ml	>480
Methotrexate	59-05-2	25 mg/ml	>480
Paclitaxel	33069-62-4	6 mg/ml	>480
Thio-Tepa	52-24-4	10 mg/ml	0.5

Permeation rate 0.01 µg/cm²/min

Permeation breakthrough times according to EN 16523-1

CHEMICAL AGENT	CAS NUMBER	MEAN BREAKTHROUGH TIME (MINUTES)	PROTECTIVE INDEX	PART
Sodium Hydroxide NaOH 40%	1310-73-2	>480*	6	Palm
Ammonia 25%	7664-41-7	20 (20, 21, 20)*	1	Palm
Formaldehyde 37%	50-00-0	>480*	6	Palm

**Breakthrough time is deemed to have occurred when the permeation rate of the challenge chemical reaches 1.0µg/cm²/min*

CHEMICAL PERMEATION SUMMARY

Historical permeation data according to EN 374-3:2003

CHEMICAL AGENT	CAS NUMBER	MEAN BREAKTHROUGH TIME (MINUTES)	PROTECTIVE INDEX	PART
Ethanol 70%	64-17-5	61 (56, 70, 58)*	3	Palm
Isopropyl Alcohol (IPA) 70%	67-63-0	53 (50, 56, 54)*	2	Palm

**Breakthrough time is deemed to have occurred when the permeation rate of the challenge chemical reaches 1.0µg/cm²/min*

RATING SYSTEM						
0	1	2	3	4	5	6
<10	10-30	30-60	60-120	120-240	240-480	>480
NOT RECOMMENDED	SPLASH PROTECTION		MEDIUM PROTECTION		HIGH PROTECTION	

Data given in the table above are based on results of laboratory tests performed on the palm or cuff area of the glove. These tests were run using standard test methods that may not adequately replicate any specific conditions of end use. We wish to highlight that permeation times do not equate to safe wear time. Because Ansell has no detailed knowledge or control over the conditions of end use, any of these data must be advisory only, and Ansell must decline any liability.

Contact your Ansell representative for ordering or more information.

North America
US Tel: 800 952 9916
CA Tel: 1-844-494-7854
Email: insidesalesus@ansell.com

Central & South America
Tel: +52(442) 296 20 50
Email: cslac@ansell.com

Brazil
Tel: +55-11-3356-3100
Email: luvas.medicas@ansell.com

Europe, Middle East & Africa
Tel: +32 (0) 2 528 74 00
Email: info@ansell.eu

Asia Pacific
Tel: +603 8310 6688
Email: apac.medical@ansell.com

Australia & New Zealand
Tel: +61 3 9270 7270
Email: protection@ap.ansell.com

ansell.com

Sterility Validation Statement
BioClean™ Indigo Sterile Nitrile Gloves – BNPLS

Herewith, I confirm that BioClean™ Indigo Sterile Nitrile Gloves – product code BNPLS – have been sterilised using gamma irradiation to a Sterility Assurance Level (SAL) of $SAL10^{-6}$, validated using the VD_{max}^{25} method as detailed in EN ISO 11137-2.

Ansell Quality Assurance Team

Product Compliance Statement
BioClean™ Indigo Sterile Nitrile Gloves – BNPLS

Herewith, I confirm that BioClean™ Indigo Sterile Nitrile Gloves – product code BNPLS – are in conformity with the requirements of the Personal Protective Equipment Regulation (EU) 2016/425 and are processed in a facility operating a Quality Management System compliant with Annex VIII (Module D) of the regulation and certified by SGS (certificate number MY18/1102977957) as well as ISO 9001:2015 (certificate number MY08/75286).

They are processed in a NEBB certified ISO Class 4 cleanroom environment compliant with the requirements of ISO 14644.

Ansell Quality Assurance Team

VIRAL PENETRATION RESULT SUMMARY

Resistance to Penetration by Blood Borne Pathogens Statement
BioClean™ Indigo Sterile Nitrile Gloves – BNPLS

Herewith, I confirm that BioClean™ Indigo Sterile Nitrile Gloves have been tested against EN 374-5: 2016; *Protective gloves against dangerous chemicals and micro-organisms* – Part 5: *Terminology and performance requirements for micro-organism risks* and ISO 16604:2004; *Clothing for protection against contact with blood and body fluids — Determination of resistance of protective clothing materials to penetration by blood-borne pathogens — Test method using Phi-X 174 bacteriophage*, using test Procedure B.

The result of the test for Resistance to Penetration by Blood Borne Pathogens was PASS (no penetration of bacteriophages through the test specimen).

Ansell Quality Assurance Team

PRODUCT STATEMENT

Nitritex Ltd.
Company Registration No. 03231971 (England & Wales)
VAT No. GB 676 8083 88

Ground Floor,
15 Kings Court, Willie Snaith Road
Newmarket, Suffolk, CB8 7SG
United Kingdom

T. + 44 (0) 1638 663338
F. + 44 (0) 1638 668890
Info@nitritex.com
www.ansell.com

Product Declaration

February 2021

Nitritex Ltd hereby declares that in accordance with the guideline EMEA/410/01 there are no animal derived components used within the manufacture or processing of the below BioClean product/s:

Product Code: **BNPLS**
Production Description: **BioClean Indigo Nitrile Cleanroom Gloves**

As such, this product is therefore declared free of Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE).

There are no known or detected Ribonucleic Acid (RNA) or Genetically Modified Organisms (GMO) derivatives present in the ingredients used.

Declaration approved when stamped here:

Nitritex Ltd
Ground Floor, 15 Kings Court
Willie Snaith Road
Newmarket, Suffolk
CB8 7SG UK
Company Reg. No. 3231971

EN	ES	IT	NL
DA	NO	AR	JP
FR	DE	PT	EL
FI	SV	RU	UA
CS	HU	LV	PL
BG	SL	KOR	TH
ET	LT	MT	RO
SK	TR	MS	ZH

BioClean™ Profile™ Omega™

INSTRUCTIONS FOR USE

Ansell

EN

INSTRUCTIONS FOR USE

BioClean™ Profile™ Omega™

Single use Category III gloves

This instructions for use note is to be used in combination with the specific information that is mentioned on each packaging enclosure.

These gloves are designed to protect the hands mainly against chemical splashes and comply with the applicable harmonised EN or EN ISO Standards as shown by the pictograms being mentioned on the packaging.The gloves therefore will provide protection against the specific risks as shown by the pictograms which are defined by these harmonised standards.

The gloves are in conformity with the European Regulation 2016/425.

Gloves which are accompanied with the pictogram which designates contact with foodstuffs, are also in conformity with the European Regulations 1935/2004 and 2023/2006 for Food-contact materials.

Please ensure the gloves are used only for the designated purposes, as explained above.

Explanation of symbols and pictograms used on glove packaging:

ISO 374-1/Type B or C  XYZ	**Type B** = chemical breakthrough time > 30 minutes against at least 3 chemicals as indicated by the code letters shown below the pictogram. Performance level and test chemicals are detailed on the glove packaging. **Type C** = chemical breakthrough time > 10 minutes against at least one test chemical as detailed on the glove packaging (no code underneath the pictogram).	 LATEX	**WARNING.** When the packaging includes this pictogram, the glove contains Natural Rubber Latex which may cause allergic reactions including anaphylactic responses.
EN 420: 2003 +A1: 2009 	Please read the Instructions for Use, prior to using the gloves, or contact Nitritex for more information		Suitable for contact with foodstuffs. Any limitations are detailed on the glove packaging.
ISO 374-5: 2016 	Protection against bacteria and fungi, not tested against virus. AQL and Performance level are detailed on the glove packaging.	ISO 374-5: 2016  VIRUS	Protection against bacteria, fungi and virus. AQL and Performance level are detailed on the glove packaging.
EN 421: 2010 	Protection against radio-active contamination AQL and Performance level are detailed on the glove packaging.	EN 16350 	EN 16350: 2014 Gloves meeting the requirement (vertical resistance < 10^5 ohm) for use in areas where flammable or explosive areas exist.
CE 0598	Module D Certification carried out by: SGS Fimko Oy, P.O. Box 30 (Särkiniementie 3), 00211 HELSINKI, Finland Notified Body No. 0598		Single use only – DO NOT REUSE
	Protect from heat and radioactive sources		Protect from sunlight
	Maximum storage temperature, 40°C		Do not use if package is damaged
	Manufacturer	IMPORTER	Importer in EU & UK

The EU Declaration of conformity may be downloaded from:
www.ansell.com/regulatory
www.profile-omega.com/products/all/product code

EU Type examination carried out by:
Centexbel-Gent, Technologiepark 70, BE-9052 Zwijnaarde (Gent), Belgium.
Notified Body Number 0493

Warnings!

- This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals.
- The chemical resistance has been assessed under laboratory conditions from samples taken from the palm and the cuff and relates only to the chemical tested. It can be different if the chemical is used in a mixture.
- It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on temperature, abrasion and degradation.
- When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves.
- The electrostatic properties of the protective gloves might be adversely affected by aging, wear, contamination and damage, and might not be sufficient for oxygen enriched flammable atmospheres where additional assessments are necessary.
- Electrostatic dissipative protective gloves shall not be unpacked, opened, adjusted or removed whilst in flammable or explosive atmospheres or while handling flammable or explosive substances.
- The person wearing electrostatic dissipative protective gloves shall be properly earthed, e.g. by wearing adequate footwear.
- Before usage, inspect the gloves for any defect or imperfections.
- These gloves do not protect against mechanical risks.
- These gloves do not protect against ionising radiation.
- These gloves are not intended for use in radioactive containment enclosures.

Contact your Ansell representative for ordering or more information.

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