Dossier d'information type Euro Pharmat

DISPOSITIF MEDICAL

Remarque : Selon le dispositif médical (DM) concerne, ce dossier concernera une référence, un type ou une famille de DM

1. Renseignements administratifs concernant l'entreprise		***Date de mise à jour : 03/11/2016*** ***Date d'édition :03/11/2016***
1.1	**Nom** : Laboratoires EUROMEDIS	
1.2	**Adresse complète** : Z.I. de la Tuilerie 60290 NEUILLY -SOUS- CLERMONT	**Tel:** +33 344738360 **Fax** : +33 344735732 **e-mail** : euromedis@euromedis.fr **Site internet** : www.euromedis.fr
1.3	**Coordonnées du correspondant matériovigilance** : M. Eddie ZERBIB Responsable qualité	**Tel** : +33 344738360 **Fax** : +33 344735732 **e-mail** : eddie.zerbib@euromedis.fr

2. Informations sur dispositif ou équipement		
2.1	**Dénomination commune** : selon la nomenclature d' Europharmat®	
2.2	**Dénomination commerciale** : FLEXISKIN® GANT EXAMEN NITRILE BLEU COBALT SANS POUDRE 240 mm	
2.3	**Code nomenclature** :11882	
2.4	**Code LPPR*** (ex TIPS si applicable) :	
2.5	**Classe du DM** : Classe I **Directive de l'UE applicable** : 93/42/CE **Selon Annexe n°** : IX chapitre 3 et VII chapitre 3 Déclaration CE de conformité	**Catégorie de l'EPI** : Catégorie III **Directive de l'UE applicable** : 89/686/CE **Selon Annexe n°** : chapitre II article 11 Certificat CE0465 du CIMAC
	Date de première mise sur le marché dans l'UE : 08/2016 **Fabricant du DM** : Laboratoires EUROMEDIS **Certificat applicable à l'entreprise fabricante** : ISO 9001 : 2008 et ISO 13485 : 2003 **Organisme certificateur** : LNE/G-MED **Normes applicable au dispositif médical** : - Directive 93/42 CE pour les dispositifs médicaux EN 455-1/2/3/4- Gants médicaux non réutilisables - Directive 89/686 CE Pour les équipements de protection individuels EN 374-1/2/3- Gants de protection contre les produits chimiques et les micro-organismes EN 420- Gants de protections exigences générales et méthodes d'essais EN 388 - Gants de protection contre les risques mécaniques	

Dossier d'information type Euro Pharmat

DISPOSITIF MEDICAL

2.6

Descriptif du dispositif (avec photo, schéma, dimensions, volume, …): peut être relié au point 8 : selon fiche technique.

Gant nitrile bleu-cobalt offrant une très bonne résistance aux agressions des produits chimiques et une souplesse étonnante permettant un toucher de grande sensibilité

Gant d'examen ambidextre existe en 5 tailles T 5/6 - T 6/7 - T 7/8 - T 8/9 - T 9/10

Usage Unique : Oui
Couleur : Bleu- Violet
Texture : extrémité distale rugueuse
Forme : Ambidextre
Bord : Roulé

Alimentaire : Oui sauf pour les amines
Code couleur sur le packaging : Oui, voir tableau des dimensions.
Origine : Asie du Sud Est
Trousse : Non

Dimension du dispositif : (Voir annexe 1)

Taille		Longueur en mm Mini	Périmètre de la paume en mm	Epaisseur en mm (±0.01)		
				Manchette	Paume	Doigt
T 5/6	XS	240	70-79	0.05	0.05	0.09
T 6/7	S	240	80-89	0.05	0.05	0.09
T 7/8	M	240	90-99	0.05	0.05	0.09
T 8/9	L	240	100-109	0.05	0.05	0.09
T 9/10	XL	240	110-119	0.05	0.05	0.09

2.7

Références Catalogue :
Pour chaque référence préciser :

REFERENCE :

Conditionnement / emballages

UCD (Unité de Commande) : La boite
CDT (Multiple de l'UCD) : Quantité par carton
QML (Quantité minimale de livraison) : Le carton

Spécification du produit	Référence	Unité s/ boîte	Boîtes / carton	Unités / carton
T 5/6	127595	100	10	1000
T 6/7	127596	100	10	1000
T 7/8	127597	100	10	1000
T 8/9	127598	100	10	1000
T 9/10	127599	100	10	1000

2.8

Composition du dispositif et Accessoires :

Latex : Non
Agent de vulcanisation : Oui
Présence de DEHP: Non
Produit d'origine animale ou biologique : Non

- Nitrile
- Phtalocyanine blue
- Oxyde de Zinc
- Sulphure
- Dioxide de titanium
- Zinc dibutyldithiocarbamate
- Hydroxyde de potasium

Dispositifs et accessoires associés à lister. NA

Dossier d'information type Euro Pharmat

DISPOSITIF MEDICAL

Caractéristiques de la référence :

Norme	Essai	Résultats
EN 455-1	Etanchéité	Niveau inspection 1 : AQL=1.5
EN 455-2	Force minimale à la rupture	
	- Avant vieillissement accéléré	≥ 6 N
	- Après vieillissement accéléré:	≥ 6 N
EN 455-3	Taux de poudre résiduel	<2 mg/gant
EN 455-3	Taux de protéine	Indétectable
EN 455-4	Détermination de la durée de conservation	5 ans
EN 374-1	Terminologie	Conforme
EN 374-2	Essai de fuite à l'eau	Conforme
EN 374-2	Essai de fuite à l'air	Conforme
EN 374-3	(L) Acide sulfurique 96%	> 30 min index 2
	(K) Hydroxyde de sodium 40%:	> 90 min index 3
	(G) Diethylamine	> 30 min index 2
EN 420	Taille et dimension	OK
EN 388	Résistance à l'abrasion	Niveau de performance = 0
	Résistance à la coupure	Niveau de performance = 0
	Résistance au déchirement	Niveau de performance = 0
	Résistance à la perforation	Niveau de performance = 0
ISO 10993-1	Cytotoxicité	Conforme
	Sensibilisation	Conforme
	Irritation	Conforme
ASTM D 6978-05	Test des drogues de chimiothérapie	Testé voir page5
ASTM F 1671-07	Penetration viral et bactériologique	Testé voir page10
Alimentarité		
Directive 2002/72/CE du 6/08/2002	-Essai de migration globale	voir page 11, la déclaration de conformitéà la réglemenatation relative aux matériaux des matériels et équipements au contact des denrées alimentaires

Résultats du rapport PN109972B (page 5) du test de permèation suivant l'ASTM D 6978 (EN 374-3)

CYTOTOXIQUE	Indice de performance à la perméation
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	0
Cisplatin, 1.0 mg/ml (1,000 ppm)	5
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000ppm)	5
Dacarbazine (DTIC), 10.0 mg/m1(10,000 ppm)	5
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	5
Etoposide (Toposar), 20.0 mg/m1 (20,000 ppm)	5
Fluorouracil, 50.0 mg/ml (50,000 ppm)	5
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	5
Thiotepa, 10.0 mg/m1 (10,000 ppm)	2

Tableau 1 — Indices de performance à la perméation

Temps de passage mesuré (min)	Indice de performance à la perméation
> 10	1
> 30	2
> 60	3
> 120	4
> 240	5
> 480	6

Dossier d'information type Euro Pharmat

DISPOSITIF MEDICAL

2.9	**Domaine - Indications :** Domaine d'utilisation: Médical et Industriel Indications: Gant examen résistant aux agents chimiques

3. Procédé de stérilisation :	
	DM stérile : Non

4. Conditions de conservation et de stockage	
	Conditions normales de conservation & de stockage : ne doit pas être exposé à l'humidité et au soleil Précautions particulières : Usage unique Durée de la validité du produit : 5 ans Présence d'indicateurs de température s'il y a lieu : NA

5. Sécurité d'utilisation	
	Sécurité technique : Conforme aux normes EN 455-1/2/3/4, EN 374-1/2/3et EN 420
	Sécurité biologique: NA

6. Conseils d'utilisation	
6.1	**Mode d'emploi :** NA
6.2	**Indications :** (destination marquage CE) Examen Médical - Protection du patient et de l'utilisateur lors de soins
6.3	**Précautions d'emploi :** Ne pas ouvrir avec un objet coupant
6.4	**Contre- Indications :** NA

7. Informations complémentaires sur le produit	
	Bibliographie, rapport d'essais cliniques, ou d'études pharmaco-économiques, amélioration du service rendu : recommandations particulières d'utilisation (restrictions de prise en charge, plateau technique, qualification de l'opérateur, etc.) … : Toutes les informations se trouvent dans le dossier technique

8. Liste des annexes au dossier (s'il y a lieu)	
	- Etiquetage et étiquette de traçabilité (le cas échéant) Etiquetage conforme à la directive

Testing. Development. Problem Solving.

AKRON RUBBER DEVELOPMENT LABORATORY, INC.

July 17, 2013

· TEST REPORT ·

PN 109972B

CHEMICAL ANALYTICAL SERVICES

Prepared For:

Prepared By: Tiffany L. Heller
Assistant Manager
Pharmaceutical Services

Approved By: Ana C. Barbur, M.S.
Manager
Chemical, Microbiological, & Pharmaceutical Services

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July 17, 2013

SUBJECT: Permeation testing per ASTM D 6978-05 on sample submitted by the above company.

RECEIVED: Glove sample identified as Powder Free Nitrile Examination Gloves; Lot# S2123286 (32BP), Size Medium.

TESTING CHEMOTHERAPY DRUGS:

Table 1. List of the Testing Chemotherapy Drugs, Sources, and Expiration Dates

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
Carmustine (BCNU)	Bristol-Myers, Lot# 2C7009A, Expiration 07/2015
Cisplatin	Pfizer, Lot# 7800808, Expiration 08/2013
Cyclophosphamide (Cytoxan)	Sigma, Lot# SLBC0668V, Expiration 03/2014
Dacarbazine (DTIC)	APP, Lot# 6103390, Expiration 02/2014
Doxorubicin Hydrochloride	USP, Lot# L0K258, Expiration 06/2014
Etoposide (Toposar)	Teva, Lot# 31314884B, Expiration 02/2015
Fluorouracil	APP, Lot# 6104355, Expiration 01/2014
Paclitaxel (Taxol)	Hospira, Lot# Z096865AA, Expiration 04/2014
Thiotepa	Sigma Aldrich, Lot# SLBD4239V, Expiration 10/2014

COLLECTION MEDIA:
The collection media, which were selected, are listed in Table 2.

Table 2. Collection Media for Testing Chemotherapy Drugs

TEST DRUG AND CONCENTRATION	COLLECTION MEDIUM
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	10% Ethanol Aqueous Solution
Cisplatin, 1.0 mg/ml (1,000 ppm)	Distilled Water
Cyclophosphamide (Cytoxan), 20 mg/ml (20,000 ppm)	Distilled Water
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	Distilled Water
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	Distilled Water
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	Distilled Water
Fluorouracil, 50.0 mg/ml (50,000 ppm)	9.20 pH Sodium Hydroxide Solution
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	30% Methanol Aqueous Solution
Thiotepa, 10.0 mg/ml (10,000 ppm)	Distilled Water

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TESTING CONDITIONS:

Standard Test Method Used:	ASTM D 6978-05
Analytical Method:	UV/VIS Spectrometry
Testing Temperature:	35.0°C ± 2.0
Collection System:	Closed Loop
Specimen Area Exposed:	5.067 cm2
Selected Data Points:	25/test
Number of Specimens Tested:	3/test
Location Sampled From:	Cuff area
Comments/Other Conditions:	Magnetic stir bar was used in the sampling chamber

DETECTION METHOD OF CHEMICAL PERMEATION: UV/VIS ABSORPTION SPECTROMETRY:
Instrument: Perkin Elmer UV/VIS Spectrometer Lambda 25

UV/VIS Absorption Spectrometry was used to measure the absorbance of test chemicals, which permeated through the specimens into the collection medium. The collection medium was circulated in a closed loop at 11 ml/minute of flow rate through the testing period. Data collection was performed according to the programmed schedule by means of UV Winlab software from the Perkin Elmer Corporation. The list of the characteristic wavelengths is shown below

Table 3. Characteristic Wavelengths used in UV/VIS Absorption Spectrometry

TESTING CHEMOTHERAPY DRUGS	WAVELENGTH (nm)
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	229
Cisplatin, 1.0 mg/ml (1,000 ppm)	199
Cyclophosphamide (Cytoxan), 20 mg/ml (20,000 ppm)	200
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	320
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	232
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	205
Fluorouracil, 50.0 mg/ml (50,000 ppm)	269
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	231
Thiotepa, 10.0 mg/ml (10,000 ppm)	199

SAMPLE CHARACTERISTICS:

Table 4. Thickness characteristics for the tested specimens. Powder Free Nitrile Examination Gloves; Lot# S2123266 (32BP), Size Medium

Testing Chemotherapy Drugs	Thickness (mm)			Average (mm)	Weight/Unit Area (g/m2)
	Sample 1	Sample 2	Sample 3		
Carmustine (BCNU)	0.060	0.065	0.055	0.060	58.4
Cisplatin	0.058	0.062	0.057	0.059	58.4
Cyclophosphamide (Cytoxan)	0.070	0.060	0.060	0.063	58.4
Dacarbazine (DTIC)	0.061	0.063	0.059	0.061	58.4
Doxorubicin Hydrochloride	0.066	0.063	0.057	0.062	58.4
Etoposide (Toposar)	0.064	0.057	0.058	0.060	58.4
Fluorouracil	0.060	0.059	0.058	0.059	58.4
Paclitaxel (Taxol)	0.063	0.063	0.058	0.061	58.4
Thiotepa	0.057	0.060	0.065	0.061	58.4

RESULTS:

Table 5. Permeation Test Results on Powder Free Nitrile Examination Gloves, Lot# S2123266 (32BP), Size Medium

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)	STEADY STATE PERM. RATE (Specimen 1/2/3) (µg/cm²/minute)	OTHER OBSERVATIONS
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	1.0 (1.2,2.1,1.0)	2.1 (2.3,2.0,2.0)	Moderate swelling and no degradation
Cisplatin, 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Cyclophosphamide (Cytoxan), 20 mg/ml (20,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Fluorouracil, 50.0 mg/ml (50,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	No breakthrough up to 240 min.	N/A	Moderate swelling and no degradation
Thiotepa, 10.0 mg/ml (10,000 ppm)	31.3 (45.5,31.3,46.4)	1.1 (1.4,0.6,1.2)	Slight swelling and no degradation

Tiffany L. Heller
Assistant Manager
Pharmaceutical Services
AKRON RUBBER DEVELOPMENT LABORATORY, INC

Ana C. Barbur, M.S.
Manager
Chemical, Microbiological and Pharmaceutical Services

ASTM F 1671-07 - Penetration viral et bactériologique

LEMBAGA GETAH MALAYSIA
Malaysian Rubber Board
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148, Jalan Ampang, 50450 Kuala Lumpur, Malaysia.
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E-mail : general@lgm.gov.my Web-site : http://www.lgm.gov.my

ISO 9001 : 2008
Certificate No : AJAMY06/1198

TEST REPORT

REPORT NUMBER : USTL/2014/05/0001 DATE: 22/6/14

SUBJECT : VIRUS PENETRATION TEST

RECEIVED ON : 9 May 2014

These results have been obtained on sample(s) submitted to us.

Condition of samples	: Unused gloves with no wear or abrasion
Expected	: No penetration of viral solution from inside the glove; any penetration above 10 pfu is considered failed. Expected recovery; 100 ± 2%
Test objective	: To determine that the viral solution did not penetrate > 10 pfu within the test period (viral leak < 10 pfu)

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E-mail : general@lgm.gov.my Web-site : http://www.lgm.gov.my

ISO 9001 : 2008
Certificate No :
AJAMY08/1198

TEST REPORT

REPORT NUMBER : USTL/2014/05/0001 DATE: 22/6/14

SAMPLE DESRIPTION : **Powder Free Nitrile Examination Gloves**

Lot No: 8418291132

STANDARD TEST METHOD : *ASTM F1671-07*, Phi-X174 Bacteriophage Penetration Test

DATE OF TESTING : 10 June 2014

No.	Sample Id	Plague Forming Unit	Requirement Virus Leak (Pfu)	Status
1	**Powder Free Nitrile Examination Gloves Lot No: 8418291132**	**NP**	**<10**	**PASS**

Note
NP : No plaque formed
VSF : Test results are acceptable if VSF > 0.8*

Disclaimer
Test is performed to required specification (s) of the said standard (where applicable). Results reflect data obtained and/or observed from the samples provided for testing only. Results do not reflect shipment prior to the stated lot numbers, or condition of future shipment, nor does it reflect the quality of future production and manufacturing. Our organization is not liable for any mis-used of data or information

Yours Sincerely;

(TAJUL ANUAR YAAKOB)
Research Officer
47000 Sg Buloh
Selangor, Malaysia

Dossier d'information type Euro Pharmat

DISPOSITIF MEDICAL

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Reg. Imprese n° 229059
Trib. di Milano
R.E.A. n° 1147818

CIMAC
Centro Italiano
Materiali di Applicazione
Calzaturiera

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

PRD N° 0171 B

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC

Signatory of EA, IAF and ILAC
Mutual Recognition Agreements

Sede operativa: 27029 VIGEVANO (PV) - C.so G. Brodolini, 19 - Tel. 0381.84722 - Fax 0381.73393 - E-mail: info@cimaconline.com - Internet: http://www.cimaconline.com

According to the EEC instruction 89/686 dated 21st of December 1989, concerning the standardisation of legislation of all Member Countries with regards to individual protection system and the relative legislative decree datred 4th of December 1992, N°. 475,

A.N.C.I. Servizi s.r.l. a socio unico - C.I.M.A.C. section
CENTRO ITALIANO MATERIALI DI APPLICAZIONE CALZATURIERA
Authorized with the decree issued by the Ministry of Industry of the Italian Republic
On the 11th of October 2000 – Community identification N°. 0465

grants:

CLOSURE REPORT OF EC CERTIFICATION

N° 0162/24024/16 - 00863C

MODULE C2 – EC TYPE CONFORMITY BASED ON INTERNAL PRODUCTION CONTROL WITH TESTS MADE UNDER CONTROL OFFICER AT RANDOM INTERVALS

For the following model of personal protective equipment of Cat. III:

Protective glove against chemicals and micro organism - Article "FLEXISKIN bluple nitrile glove 240 mm"

Manufacturer (see notes):

LABORATOIRES EUROMEDIS

ZA DE LA TUILERIE
60290 NEUILLY SOUS CLERMONT

The validity of the closure report shall be subject to surveillance activities provided for by Directive 89/686/EEC, to be implemented within 12 months from the issue date specified below.

Vigevano, 23 May 2017

Responsible of CE Certification of Glove
Dr. Sandro Milanesi

The Technical Responsible
Ing. Giuseppe Bellotti

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a socio unico
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1. Description of personal protective equipment:

Category of PPE: third category
Attestato di certificazione CE del tipo 0162/24024/16
Type of PPE: Protective glove against chemicals and micro organism
In compliance with EN 374: 2003 Part I II and III
Protection against anti neoplastic agents
Model of glove: glove with five fingers
Size range: from 6 to 10 (from XS to XL)
Manufacturing process: dipping

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2. The tests and the examinations to verify the conformity of the article (in compliance with art. 11A of Directive 89/686/EEC – Decision 768/08/EC Module C2) are performed applying the following harmonized standards:

Standards applied:

A - EN 420:2003 + A1: 2009 – General requirements for gloves.
B - EN 374:2003 part I II e III – Glove against chemicals and micro organism
C - EN 388:2016 – Protective gloves against mechanical risk.

3. The results of tests and examinations are contained in the following test reports:

C.I.M.A.C. 2017/0936-RP -1-RP-1 Dated 23 of May 2017

4. Requirements of the personal protective equipment:

Based on the test carried out, the model of PPE examined is conform to the model described in the CE type certificate and that there is uniformity in production activities.

The model of protective glove against chemicals and micro organism - Article "FLEXISKIN bluple nitrile glove 240 mm" conforms:

- the requirements of EN 420:2003 + A1 2009 standard, points 4.1, 4.2, 4.4, 5 and 5.2;

- the following permeation levels as specified in EN 374:2003 Part I standard;

- the following permeation performance levels as specified in EN 374:2003 Part I;

	Performance level
Sulphuric acid solution at 96%	2
Sodium hydroxide solution at 40%	3
Dyethilammine	2

- the performance levels as specified in prospectus 1 of EN 388:2016 standard;

		Performance level
6.1	Abrasion resistance	0
6.2	Cut resistance	0
6.3	Tear resistance	0
6.4	Puncture resistance	0
5.2	Dexterity	5

In the model of Personal Protective Equipment and its components was not detected the presence of dangerous substances listed in Annex XVII of Regulation 1907/2006/EC and subsequent amendments and additions.

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5. Marking of the personal protective equipment:

The following information is provided on the box of the glove:

- the "CE" mark
- the article code: FLEXISKIN bluple nitrile glove 240 mm
- the manufacturer name: LABORATOIRES EUROMEDIS
- the glove size
- the symbols concerning the protection provided: Protective gloves against chemicals and micro organisms.
- the permeation performance levels as specified in EN 374:2003 Part I standard:

	Performance level	Code
Sulphuric acid solution 96%	2	L
Sodium Hydroxide solution 40%	3	K
Dyethilammine	2	G

- the performance levels as specified in prospectus 1 of EN 388:2016 standard;

		Performance level
6.1	Abrasion resistance	0
6.2	Cut resistance	0
6.3	Tear resistance	0
6.4	Puncture resistance	0
5.2	Dexterity	5

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Cap. Soc.: € 10.400 i.v.
C.F./P.I.: 07199040150
Reg. Imprese n° 229059
Trib. di Milano
R.E.A. n° 1147818

CIMAC
Centro Italiano
Materiali di Applicazione
Calzaturiera

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

PRD N° 0171 B

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC

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6. Notes:

- "*making available on the market*" shall mean any supply of a product for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge.
- "*placing on the market*" shall mean the first making available of a product on the Community market.
- "*manufacturer*" shall mean any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark.
- "*authorised representative*" shall mean any natural or legal person established within the Community who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks.
- "*harmonised standard*" shall mean a standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC on the basis of a request made by the Commission in accordance with Article 6 of that Directive.
- "*accreditation*" shall mean an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity.
- "*conformity assessment*" shall mean the process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled.
- "*recall*" shall mean any measure aimed at achieving the return of a product that has already been made available to the end user.
- "*withdrawal*" shall mean any measure aimed at preventing a product in the supply chain from being made available on the market.
- "CE *marking*" shall mean a marking by which the manufacturer indicates that the product is in conformity with the applicable requirements set out in Community harmonisation legislation providing for its affixing.
- The content of this EC Type-Examination Certificate is referred to the tested personal protective equipment only.
- This EC Type-Examination Certificate may be integrally duplicated; the copy must be faithful, legible (if pint size) and must contain the bold caption "TRUE COPY".

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LAB N° 0005

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LABORATOIRES EUROMEDIS

ZA de la TUILERIE
NEUILLY sous CLERMONT
60290

TEST REPORT: RP 2017/0936-1-RP-1 of 23/05/2017 **Page 1 of 4**

SAMPLE RECEIVED ON: 10/05/2017

SAMPLE RECEIVED FOR TESTING:

Protective glove against chemicals and micro organism - Article "FLEXISKIN bluple nitrile glove 240 mm"

TEST REQUESTED:

Determination of the characteristics according with EN 374:2003 Part I II e III standard
Determination of the characteristics according with EN 388: 2016

EMISSIONE	P. BIGLIA	S. MILANESI
OGGETTO	**RESPONSABILE LAB. FISICO MECCANICO**	**RESPONSABILE LAB. ANALISI CHIMICHE**

Il campionamento del materiale ricevuto da esaminare, se non diversamente indicato, è stato effettuato dal cliente.

Il residuo del campione analizzato si conserva per tre mesi.

Il Rapporto di Prova non ha validità di approvazione e/o certificazione del campione esaminato.

Il marchio ACCREDIA e/o l'Accreditamento del CIMAC non possono essere utilizzati nella documentazione di prodotto a meno che non venga riportata copia integrale, fedele, leggibile del rapporto di prova contenente la dicitura in grassetto "Copia Conforme all'Originale".

Il CIMAC è accreditato da ACCREDIA con il numero di accreditamento 0005. Per le prove accreditate il ACCREDIA garantisce la competenza del personale, la disponibilità di strumentazione e la conformità delle procedure di prova alla norma/procedura richiamata.

Il contenuto del presente Rapporto di Prova si riferisce unicamente al campione sottoposto a prova.

Le prove riportate nel presente Rapporto di Prova contrassegnate dalla dicitura " Non accreditate da ACCREDIA" non rientrano nell'Accreditamento.

Physics-mechanical laboratory and chemical analysis
Tests carried out from 11.05.17 to 23.05.17

No. 500 samples of protective gloves against chemicals and micro organism sampled by CIMAC at the storage center of Laboratoires Euromedis – Z.A de la Tuilerie – 60290 Neuilly sous Clermont on 09.05.2017

Determination of the characteristics according to EN 374:2003 Part I II and III standard.
Determination of the characteristics according to EN 388:2016

Periodic control of PPE – Batch number: SU1609976

Reference to test register: from F/5419 to F/5421

Items of EN 420:2003 + A 1 2009

4 General

4.2 Construction	The material and the construction are such that do not decrease the general performances of the glove.

4.4 Innocuousness of protective gloves

Palm - Back
(Nitril - cod. Bluple nitrile)

5 Comfort and efficiency

5.1 Sizes

5.1.2 Sizes and measures of gloves

Length of the glove	size 6 left = 240 mm	size 6 right = 220 mm
	size 8 left = 250 mm	size 8 right = 250 mm
	size 11 left = 260 mm	size 11 right = 260 mm

5.2 Dexterity

The smallest diameter of pin fulfilling test condition is 5 mm.

Item of EN 374:2003 Part II

5.2 Air leak test

6 The glove pass the test

5.3 Water leak test

6 The glove pass the test

Item of EN 374:2003 Part III

8.4 Assessment of breakthrough time

8.5.1 Tested chemical product: Sulphuric acid
Révélation technique: potentiometrical analyses
Concentration of test solution : 96% by weight
Test temperature: 23 ± 2°C
Sample from the palm of the glove
Average thickness of the sample = 0.08 mm
Collection agent: water.
Sample appearance after testing: colour variation – turn to brown – sample brittle
Results:
After 30' it is not verified the passage of the tested chemical product Sulphuric acid in the collection agent in quantity over 1µg min^{-1} cm^{-2} (passage occur at 35')

Items of EN 388:2016 (*)

Results:

Palm – Back
(Nitril - cod. Bluple nitrile)

4.0 Requirements
Table "1"

6.1 Abrasion resistance Before 100 test cycles the surface of the specimens is broken.

6.2 Blade cut resistance

Sequence	Check specimen C	Specimen T	Check specimen C	Index I_n
1A	2	0	2	1.0
2A	2	0	2	1.0
3A	2	0	2	1.0
4A	2	0	2	1.0
5A	2	0	2	1.0

Sequence	Check specimen C	Specimen T	Check specimen C	Index I_n
1B	2	0	2	1.0
2B	2	0	2	1.0
3B	2	0	2	1.0
4B	2	0	2	1.0
5B	2	0	2	1.0

Minimum index = 1.5

6.3 Tear resistance

Specimens taken in direction of the length of the palm of the glove	8 N
	9 N
Specimens taken in direction of the width of the palm of the glove	6 N
	5 N

6.4 Puncture resistance

Specimen "1"	7 N
Specimen "2"	6 N
Specimen "3"	5 N
Specimen "4"	6 N

(*) – test not accredited by ACCREDIA

* End of Test Report *