Dossier d'information type Euro Pharmat

DISPOSITIF MEDICAL

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

1. Renseignements administratifs concernant l'entreprise	*Date de mise à jour : 27/09/2017* *Date d'édition :27/09/2017*
1.1 Nom :	

cloup

42 à 48 bd de Polangis - BP 260

94502 Champigny-sur-Marne - Cedex

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2. Informations sur dispositif ou équipement		
2.1	**Dénomination commune :** selon la nomenclature d' Europharmat®	
2.2	**Dénomination commerciale :** SENSISKIN® GANT EXAMEN NITRILE BLEU-VIOLET 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
	Numéro de l'organisme notifié : CE **Date de première mise sur le marché dans l'UE :** 12/2011 **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 374-1/2/3/4- 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 protections contre les risques mécaniques	

2.6

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

Gant nitrile bleu-violet 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	0.06	0.06	0.08
T 6/7	S	240	80-89	0.06	0.06	0.08
T 7/8	M	240	90-99	0.06	0.06	0.08
T 8/9	L	240	100-109	0.06	0.06	0.08
T 9/10	XL	240	110-119	0.06	0.06	0.08

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	Unités/ boîte	Boîtes/ carton	Unités/ carton
T 5/6	127550	100	10	1000
T 6/7	127551	100	10	1000
T 7/8	127552	100	10	1000
T 8/9	127553	100	10	1000
T 9/10	127554	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
- Phénol
- 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
	93/42/CE	
EN 455-1	Etanchéité	Niveau inspection 1 :AQL=1.5
EN 455-2	Force minimale à la rupture	
	- Avant vieillissement accéléré	≥ 6.2 N
	- Après vieillissement accéléré:	≥ 6.1 N
EN 455-3	Taux de poudre résiduel	<2 mg/gant
EN 455-4	Détermination de la durée de conservation	5 ans
ISO 10993-1	Cytotoxicité	Conforme
	Sensibilisation	Conforme
	Irritation	Conforme
	89/686/CE	
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 indice 2
	(K) Hydroxyde de sodium 40%:	>30 min indice 2
	(G) Diéthylamine	>30 min indice 2
	(J) N-Heptane	>30 min index 2
	(P) Péroxyde hydrogene 30%	>30 min index 2
	(O) Ammoniaque 25%	>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
ASTM D 6978-05	Perméation aux drogues de chimiothérapie	Testé voir résultat ci-dessous
ASTM F 1671-07	Penetration viral et bactériologique	Testé voir résultat en pièce jointe
Alimentarité		
Directive 2002/72/CE du 6/08/2002	-Essai de migration globale	Conformité à la réglementation relative aux matériaux des matériels et équipements au contact des denrées alimentaires

Résultats du rapport PN94809A du test de permèation suivant l'ASTM D 6978 (EN 374-3)

CYTOTOXIQUE	Indice de performance à la perméation
Carmustine (BCNU), 3.3 mg/mi (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/mi (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/mi (6,000 ppm)	5
Thiotepa, 10.0 mg/m1 (10,000 ppm)	0
Methotrexate, 25 mg/ml, (25,000 ppm)	5
Mitomycin C, 0.5 mg/ml (500 ppm)	5
Vincristine Sulfate, 1.0 mg/m1 (1,000 ppm)	5
Ifosfamide 50,0 mg/ml (50,000 ppm)	5
Mitoxantrone 2 mg/ml (2,000 ppm)	5

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 374-1/2/3/4, EN 388 et 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)	
	- Perméation pour les cytotoxiques - Penetration virale - Contact alimentaire - Certificat CE cat III CIMAC

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AKRON RUBBER DEVELOPMENT LABORATORY, INC.

March 24, 2011

· TEST REPORT ·

PN 94809 A

CHEMICAL ANALYTICAL SERVICES

Prepared For:

Prepared By: Tiffany L. Heller
Senior Technician

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

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

RECEIVED: Glove sample identified as Non-Sterile Blue Powder Free Nitrile Examination Gloves – Cobalt Blue, Production Date June 10, 2010, Batch# 016105A27, Size Medium.

TESTING CHEMOTHERAPY DRUGS:

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

TESTING CHEMOTHERAPY DRUGS	CHEMICAL SOURCE
Carboplatin	Teva; Lot# 10D26LA; Expiration 04/2012
Carmustine (BCNU)	Bristol-Myers; Lot# 0E7004A; Expiration 05/2013
Cisplatin	Teva; Lot# 10G23KA; Expiration 01/2012
Cyclophosphamide (Cytoxan)	Sigma; Lot# 079K1569; Expiration 12/2011
Dacarbazine (DTIC)	Hospira; Lot# X022223AA; Expiration 05/2012
Doxorubicin Hydrochloride	Ben Venue; Lot# 1827762; Expiration 01/2012
Etoposide (Toposar)	Teva; Lot# 31311001B; Expiration 02/2013
Flucrouracil	APP; Lot# 6100345; Expiration 12/2011
Ifosfamide	Baxter; Lot# 0F337A; Expiration 06/2013
Methotrexate	Intas ; Lot# K5340; Expiration 4/2011
Mitomycin C	Sigma; Lot# 048K1086; Expiration 1/2012
Mitoxantrone	Sigma; Lot# 050M1241; Expiration 12/2012
Paclitaxel (Taxol)	Hospira; Lot# W136865AB; Exp. 09/2011
Thiotepa	USP; Lot# I; Catalog# 66400; Expiration 12/2011
Vincristine Sulfate	USP; Lot# QOJ245; Expiration 08/2012

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COLLECTION MEDIA:

Table 2 Collection Media for Testing Chemotherapy Drugs

TEST CHEMICAL AND CONCENTRATION	COLLECTION MEDIUM
Carboplatin, 10 mg/ml (10,000 ppm)	Distilled Water
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), 20.0 mg/ml (20,000ppm)	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
Ifosfamide, 50.0 mg/ml (50,000 ppm)	Distilled Water
Methotrexate, 25 mg/ml, (25,000 ppm)	Distilled Water
Mitomycin C 0.5 mg/ml (500 ppm)	Distilled Water
Mitoxantrone, 2 mg/ml (2,000ppm)	Distilled Water
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	30% Methanol Aqueous Solution
Thiotepa, 10.0 mg/ml (10,000 ppm)	Distilled Water
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	Distilled Water

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)
Carboplatin	192
Carmustine	229
Cisplatin	199
Cyclophosphamide (Cytoxan)	200
Dacarbazine (DTIC)	320
Doxorubicin Hydrochloride	232
Etoposide (Toposar)	205
Fluorouracil	269
Ifosfamide (Ifex)	200
Methotrexate	303
Mitomycin C	217
Mitoxantrone	242
Paclitaxel (Taxol)	231
Thiotepa	199
Vincristine	220

TESTING CONDITIONS:

Standard Test Method Used:	ASTM D 6978-05
Deviation From Standard Test Method:	Used 1" Permeation Cell
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

SAMPLE CHARACTERISTICS:

Table 4. Thickness characteristics for the tested specimens on: Non-Sterile Blue Powder Free Nitrile Examination Gloves – Cobalt Blue. Production Date June 10, 2010. Batch# 016105A27. Size Medium.

Testing Chemotherapy Drugs	Thickness (mm) #1	#2	#3	Average (mm)	Weight/Unit Area (g/m2)
Carboplatin	0.060	0.059	0.056	0.058	55.2
Carmustine	0.054	0.057	0.055	0.055	55.2
Cisplatin	0.056	0.055	0.055	0.055	55.2
Cyclophosphamide (Cytoxan)	0.057	0.056	0.053	0.055	55.2
Dacarbazine (DTIC)	0.055	0.056	0.057	0.056	55.2
Doxorubicin Hydrochloride	0.052	0.056	0.056	0.055	55.2
Etoposide (Toposar)	0.057	0.057	0.053	0.056	55.2
Fluorouracil	0.056	0.055	0.052	0.054	55.2
Ifosfamide (Ifex)	0.058	0.056	0.056	0.057	55.2
Methotrexate	0.056	0.053	0.056	0.055	55.2
Mitomycin C	0.054	0.055	0.057	0.055	55.2
Mitoxantrone	0.055	0.054	0.057	0.055	55.2
Paclitaxel (Taxol)	0.055	0.057	0.057	0.056	55.2
Thiotepa	0.052	0.059	0.060	0.057	55.2
Vincristine	0.057	0.056	0.052	0.055	55.2

RESULTS:

Table 5. Permeation Test Results on: Non-Sterile Blue Powder Free Nitrile Examination Gloves – Cobalt Blue, Production Date June 10, 2010, Batch# 016105A27, Size Medium.

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen1/2/3) (Minutes)	AVERAGE STEADY STATE PERM. RATE (Specimen1/2/3) ($\mu g/cm^2$/minute)	OTHER OBSERVATIONS
Carboplatin, 10 mg/ml (10,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	1.82 (3.96,1.82,5.98)	2.4 (2.2,2.4,2.7)	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), 20.0 mg/ml (20,000ppm)	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
Ifosfamide, 50.0 mg/ml (50,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Methotrexate, 25 mg/ml, (25,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Mitomycin C, 0.5 mg/ml (500 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Mitoxantrone, 2 mg/ml (2,000ppm)	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)	0.93 (3.09,5.38,0.93)	1.9 (2.3,2.2,1.3)	Slight swelling and no degradation
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation

Tiffany L. Heller
Senior Technician
Pharmaceutical Services
AKRON RUBBER DEVELOPMENT LABORATORY, INC.

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

ASTM F 1671-07 : Test de Pénétration Viral et Bactériologique

VIRUAL~1

Lowenkamp R&D Laboratories Ltd — CONFIDENTIAL — Member: ASTM Int'l., IEST, A2LA, ACS; AOAC Int'l., ASQC, GAATW; IUPAC/EU, NAIS

ANALYTICAL RESEARCH
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ASTM Lab #63450

LAB LOG NO. 12- 18103 /2 CLIENT: **NO. 2**
DATE RECEIVED: June 29, 2012 CONTACT: email: ___
DATE TESTED: July 3 to July 7, 2012 ADDRESS:
PHONE: 05-679 2288 FAX: 05-679 1188

PRODUCT: Nitrile Exam Glove, On-Line Powder-Free Tex. Finger NBR (PF) F-T 8612F (C) COLOR: Blue

SPECIFICATION: ASTM F 1671-07, VIRAL PENETRATION TEST - VIRAL BACTERIOPHAGE VIA Phi-X174 SIZE: MEDIUM
RECOVERY IS EXPECTED TO BE 100% +/- 2% ALLOWANCE
SAMPLE TO BE CUT 3" Dia. MINIMUM Broth Mix = 900 to 1200 PFU's Total Mix (40 to 60 PFU's/mL)
PLAQUE FORMING UNITS (PFU) PER ML = >10 PFU/mL CONCENTRATION REPORTING LEVEL <1.0 PFU'S/mL

SAMPLE IDENTIFICATION: Batch/LOT No. NC216526B12 Pdn Date: 13/06/2012 BRAND:

TEST: VIRUAL PENETRATION 0 kPa (0 psig) 5 minutes / 13.8 kPa (2 psig) 1 minute / 0 kPa (0 psig) 54 minutes. Procedure A
GLOVES AGED AT: 24 HOURS @ 21 deg. C +/- 5 deg., Relative H 60% Samples taken from palm of glove

SEQ	BRAND NAME & DESC.	SAMPLE LOC.	SAMPLE WT (g)	SAMPLE THICK & LOT NUMBER	.01% tween 80, 250ml broth, Incubation time 20 hrs. VIRUS RECOVERY RESULTS »	SOLUTION PFU'S/mL	START 1	1 HR 2	TITER AFTER 1 HOUR	%% RECOVERY PERCENT	PASS FAIL STATUS	Date Produced Washed
1	Nitrile Exam Glove, PF Blue	PALM	0,060	SEE	900 ml @ 44 PFU's/ml	>10	<1	<1	45,900	99,8%	PASS	see lot#
		3" DIA	0,301	ABOVE								
2	Nitrile Exam Glove, PF Blue	PALM	0,060	"	900 ml @ 44 PFU's/ml	>10	<1	<1	46,000	100,0%	PASS	see lot#
		3" DIA	0,305	"								
3	Nitrile Exam Glove, PF Blue	PALM	0,060	"	900 ml @ 44 PFU'S/ml	>10	<1	<1	45,900	99,8%	PASS	see lot#
		3" DIA	0,310	"								
					AVERAGE	<1	<1	45,933				
7	CONTROL POSITIVE .045um nylon sterilitech	sheet	0,145	"	CONTROL POSITIVE	>10	<1	46,000	46,000	100%	PASS	
		3" DIA	0,358	"								
8	CONTROL NEGATIVE Mylar membrane	sheet	0,072	"	CONTROL NEGATIVE	<10	<1	<1	0,000	0%	PASS	
		3" DIA	0,314	"								

I certify that the test results are performed to the required specification(s) and only reflect data obtained and/or observed from the samples provided for testing. The results do not reflect shipments prior to the stated PO or Lot Numbers and do not reflect the condition of future shipments. UNDER THE SPECIFICATION(s) APPLIED THE PRODUCT HAS BEEN FOUND TO BE: ACCEPTABLE

NOTE: No problems observed.

DATA REVIEWED BY:

William C. Lowenkamp Jr., Ph.D. Engr. Date: July 7, 2012
President

LABORATOIRES Euromedis

NF EN ISO 13485 : 2003
ISO 9001 : 2008

Siège social

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DECLARATION DE CONFORMITE A LA REGLEMENTATION RELATIVE AUX MATERIAUX DES MATERIELS ET EQUIPEMENTS AU CONTACT DES DENREES ALIMENTAIRES, selon l'article 16 du Règlement (CE) N° 1935/2004

Je soussigné **Monsieur ROTURIER**
Société **Laboratoires EUROMEDIS**
Adresse : **Z.I. de la Tuilerie, 60290 NEUILLY-SOUS-CLERMONT**
agissant en qualité de : **Président Directeur Général**

déclare que les matériaux destinés à entrer en contact avec des denrées alimentaires et constitutifs de l'équipement référencé chez le client de la façon suivante :

Gant nitrile SENSISKIN sans poudre
Références 127550/ 127551/ 127552/ 127553/ 127554

appartiennent aux familles de matériaux suivants (listées Annexe 1 du règlement (CE) 1935/2004):Matières plastiques

Je déclare ces matériaux conformes aux exigences du Règlement (CE) N° 1935/2004 du 27/10/2004.
S'agissant des matériaux constitutifs de l'équipement décrit ci-dessus, qui se trouvent au contact direct des denrées alimentaires, cette conformité s'apprécie au regard des textes réglementaires et/ou d'autres textes de références en vigueur, listés ci-après par le déclarant :

- Directive 2002/72/CE du 6 aout 2002

Cette conformité s'entend :

- sous réserve du respect des conditions de stockage, de manutention et d'utilisation préconisées par le déclarant
- avec les restrictions suivantes le cas échéant :
  - En cas de changement des propriétés physico-chimiques des denrées alimentaires en contact avec le matériau, de modification des-dites denrées, de modification des conditions de contact (température, durée....)
  - Toute modification du matériau ou de l'équipement ou de son utilisation doit donner lieu à une réévaluation de la conformité.

Cette déclaration de conformité a été établie sur la base des éléments suivants l'essai de migration globale suivant les résultats du rapport de TÜV n° 719173559-CHM10-TSTL:

RESULTS:

Table 1 : Overall Migration Content with Food Simulants for the " Powder Free Nitrile Examination Glove, Lot no: S1222688" Sample

Type of Simulant	Testing Condition	Surface Area (dm^2)	Volume of Extractant (ml)	Overall Migration (mg/dm^2)	Commission Directive 2002/72/EC Requirement for Overall Migration Content (mg/dm^2)
1. Ultrapure Water	40°C, 2 hours	5.57	250	1.0	<10
2. 3% Acetic Acid	40°C, 2 hours	5.57	250	8.5	<10
3. 10% Alcohol	40°C, 2 hours	5.57	250	<1.0	<10
4. Olive Oil	40°C, 2 hours	5.57	250	<1.0	<10

Based on the above results, the "Powder Free Nitrile Examination Glove" sample meets the overall migration requirement under Commission Directive 2002/72/EC - "Plastic materials and articles shall not transfer their constituents to foodstuffs in quantities exceeding 10 milligrams per square decimeter of surface area of material or article (mg/dm^2) (overall migration limit)".

Code NAF 4646 Z - N° TVA intracommunautaire : FR 76 333 061 711 EORI FR 333 061 711 00037

LABORATOIRES Euromedis

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ISO 9001 : 2008

Siège social

Z.I. de la Tuilerie - 60290 NEUILLY-SOUS-CLERMONT
12, rue Pierre Bray - Tél. 03 44 73 83 60
Fax : 03 44 73 57 32
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Siret : 333 061 711 000 37

Le matériau et/ou objet référencé ci-dessus, dans des conditions normales et prévisibles d'emploi sans altérer la composition ou la détérioration inacceptable dans les caractéristiques organoleptiques de la nourriture convient uniquement aux produits avec la case cochée, à l'exception des produits exclus, ci-dessous:

- **Boissons** ■
- **Céréale, dérivés de céréales, produit de biscuiterie de la boulangerie et de la pâtisserie** ■
- **Chocolats, sucre et leurs dérivés** ■
- **Fruits et Légumes et leurs dérivés** ■
- **Graisses et huiles** ■
- **Produits, animaux et œufs** ■
- **Produits laitiers** ■
- **Produits divers** ■

Le déclarant tient à la disposition des autorités compétentes une documentation appropriée pour démontrer cette conformité.

Fait à Neuilly sous Clermont, Le 6 Mars 2013

Mathieu ROTURIER
Président Directeur Général
des Laboratoires EUROMEDIS

A.N.C.I. Servizi S.r.l.
a socio unico
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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° 0162/23853/16 - 00862C

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 "SENSISKIN 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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1. Description of personal protective equipment:

Category of PPE: third category
Attestato di certificazione CE del tipo 0162/23853/16
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 11
Manufacturing: dipped

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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 - 2-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 "SENSISKIN 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;

	Performance level
Diethyl amine	2
Sodium Hydroxide solution 40%	2
Sulphuric acid solution 96%	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 containing the gloves:

- the "CE" mark
- the identification of Competent Body: 0465
- the article code: SENSISKIN 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
Diethyl amine	2	G
Sodium Hydroxide solution 40%	2	K
Sulphuric acid solution 96%	2	L

- 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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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".

2017/0936-2-CEGC-2