# Dossier d'information type Euro Pharmat

## DISPOSITIF MEDICAL


**Note :** According to the device medical (DM) concerned, this folder will be a reference, a type or family of DM

| **1. administrative information related to the company** | | ***Date Update: 27/09/2017***<br>***Date of issue: 27/09/2017*** |
|---|---|---|
| 1.1 | **Name:** Laboratoires EUROMEDIS | |
| 1.2 | **Full address:**<br>Z.I. la Tuilerie<br>60290 NEUILLY - UNDER - CLERMONT | **Tel:** + 33 344738360<br>**Fax:** + 33 344735732<br>**e-mail:** euromedis@euromedis.fr<br>**Website:** www.euromedis.fr |
| 1.3 | **Coordinates of the corresponding materiovigilance:**<br>Mr. Eddie ZERBIB<br>Quality Manager | **Tel:** + 33 344738360<br>**Fax:** + 33 344735732<br>**e-mail:** eddie.zerbib@euromedis.fr |

| **2. information on device or equipment** | | |
|---|---|---|
| 2.1 | **Name: according to the nomenclature d' Europharmat®** | |
| 2.2 | **Trade name:**<br>SENSISKIN® BLUE-PURPLE POWDERFREE NITRILE EXAMINATION GLOVE 240 mm | |
| 2.3 | **Nomenclature code:** 11882 | |
| 2.4 | **Code PBDA * (ex if applicable TIPS)** : | |
| 2.5 | **Class of DM:** Class I<br>**Applicable EU directive:** 93/42/EC<br>**According to annex No.:** IX Chapter 3 and Chapter 3 VII<br>Declaration of conformity EC | **PPE category:** Category III<br>**Applicable EU directive:** 89/686/CE<br>**According to annex No.:** Chapter II article 11<br>Certificate CE0465 of the CIMAC |
| | **Date of first placing on the market in the EU:** 2011-12<br><br>**Manufacturer of DM:** Laboratories EUROMEDIS<br>**Applicable to the company manufacturer certificate:** ISO 9001: 2008 and ISO 13485: 2003<br>**Certifying body:** LNE/G-MED<br><br>**Standards applicable to the medical device:**<br>- Directive 93/42 EC for medical devices<br>EN 455-1/2/3/4 - non-reusable medical gloves<br>- Directive 89/686 CE for protection equipment individual<br>EN 374-1/2/3 - protective gloves against chemicals and micro-organisms<br>EN 420 - Gloves of protection General requirements and test methods<br>EN 388- Gloves of protection against mechanic risk | |

**2.6**

**Description of the device (photo, drawing, dimensions, volume,...)** : can be connected to the point 8 : according to data sheet.

Glove blue-purple nitrile offering a very good resistance to chemical aggression and an amazing flexibility allowing a touch of sensitivity

Ambidextrous examination glove is available in 5 sizes T 5/6 - T 6/7 - 7/8 - 8/9 T - T 9/10

Single use: Yes
Color: Blue - Violet
Texture: rough distal end
Shape: Ambidextrous
Edge: rolls

Food: Yes
Color code on the packaging: Yes, see size table.
Origin: South East Asia
Kit: No

Dimension of the device: (see annex 1)

| Size | | Length in mm Mini | Width in mm | Thickness in mm (±0.01) | | |
|---|---|---|---|---|---|---|
| | | | | Cuff | Palm | Finger |
| 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**

**References Catalogue** :

For each reference specify :

**REFERENCE:**

**Packaging / packaging**

**UCD** (Control unit): the box

**CDT** (Multiple of UCD): quantity per carton

**QML** (Minimum delivery quantity): carton

| The product specification | Reference | Units / box | Boxes / carton | Units / 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 of the device and accessories:**

Latex: No vulcanizing Agent: Yes
Presence of DEHP: No
Animal or biological product: No

- Nitrile
- Phenol
- Zinc oxide
- Sulphure
- Titanium dioxide
- Zinc dibutyldithiocarbamate
- Potassium hydroxide

**Devices and accessories associated with list.** NA

**Characteristics of the reference:**

| Standard | Test | Results |
|---|---|---|
| | 93/42/CE | |
| EN 455-1 | Sealing | Level 1 inspection: AQL = 1.5 |
| EN 455 - 2 | Minimum breaking force | |
| | -Before aging accelerated | 6.2 ≥ N |
| | -After aging accelerated: | 6.1 ≥ N |
| EN 455 - 3 | Residual powder rate | <0.1 mg/glove |
| EN 455 - 4 | Determination of shelf life | 5 years |
| ISO 10993-1 | Cytotoxicity | Compliant |
| | Sensibility | Compliant |
| | Irritation | Compliant |
| | 89/686/CE | |
| EN 374-1 | Terminology | Compliant |
| EN 374 - 2 | The water leak test | Compliant |
| EN 374 - 2 | Air leak test | Compliant |
| EN 374 - 3 | (L) Sulphuric acid 96% | > 30 min index 2 |
| | (K) Hydroxyde sodium40%: | > 30 min index 2 |
| | (G) Diethylamine | > 30 min index 2 |
| | (J) N-Heptane | > 30 min index 2 |
| | (P) hydrogen Peroxide 30% | > 30 min index 2 |
| | (O) Ammonia 25% | > 30 min index 2 |
| EN 420 | Size and dimension | OK |
| EN 388 | Abrasion resistance | Level 0 |
| | Cut Resistance | Level 0 |
| | Resistance to tearing | Level 0 |
| | Puncture resistance | Level 0 |
| ISO 10993-1 | Cytotoxicity | Compliant |
| | Sensibility | Compliant |
| | Irritation | Compliant |
| ASTM D 6978-05 | Chemotherapy drugs test | Tested see page5 |
| ASTM F 1671-07 | Bacteriological and viral penetration | Tested see page10 |
| | **Food** | |
| Directive 2002/72/EC of 6/08/2002 | -Test of overall migration | compliance with regulations on materials of materials and equipment in contact with foodstuffs |

Results of the report PN94809A (page 5) of the test of permeation according to the ASTM D 6978 (EN 374-3)

| CYTOTOXIC | Index to permeation |
|---|---|
| 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 |

| | |
|---|---|
| 2.9 | **Area - directions:**<br>Use: Medical and industrial<br>Information: Chemical-resistant glove review |

| 3 sterilization process: | |
|---|---|
| | **Sterile DM:** No |

| 4. conservation and storage conditions | |
|---|---|
| | Normal conditions of preservation & storage: should not be exposed to moisture and sunlight<br>Special precautions: single use<br>Duration of validity of the product: 5 years<br>Presence indicators temperature there is: NA |

| 5. operating safety | | |
|---|---|---|
| 5.1 | **Technical security** : Comply with standards EN 455-1/2/3/4, EN 374-1/2/3, EN 420 and EN 388 |
| 5.2 | **Biological safety:** NA |

| 6. usage tips | |
|---|---|
| 6.1 | **Instructions:** NA |
| 6.2 | **Information:** (destination CE marking) Protection of the patient and of the user during care |
| 6.3 | **precautions:** Do not open with an object cutting |
| 6.4 | **Contre - Indications:** NA |

| 7. additional information on the product | |
|---|---|
| | **Bibliography, report clinical trials, or pharmaco-economic studies, improvement of service: specific recommendations of ' use (support restrictions, technical platform, the operator qualification, etc.)...:**<br>All the information in the technical dossier |

| 8. list of appendices to the file (if there is one) | |
|---|---|
| | - Permeation for cytotoxics<br>- Viral Penetration<br>- CE certificate cat III CIMAC |

Testing. Development. Problem Solving.

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

An A2LA Accredited Testing Laboratory — Certificate Numbers 256.01 & 256.02
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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 |
| Fluorouracil | 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) (µg/cm²/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 |

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Ana C. Barbur, M.S.
Manager
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ASTM F 1671-07 : Test de Pénétration Viral et Bactériologique

VIRUAL-1

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

*ANALYTICAL RESEARCH*

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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 50 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 THICK & WT (g) | 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 | %% PERCENT RECOVERY | PASS FAIL STATUS | Date Produced Washed |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | Nitrile Exam Glove, PF Blue | PALM | 0,080 | SEE | 900 ml @ 46 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 | 0,080 | " | 900 ml @ 46 PFU'S/ml | >10 | <1 | <1 | 46,000 | 100,0% | PASS | see lot# |
| | | 3" DIA | 0,305 | " | | | | | | | | |
| 3 | Nitrile Exam Glove, PF Blue | PALM | 0,080 | " | 900 ml @ 46 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 sterilized | sheet | 0,145 | " | CONTROL POSITIVE | >10 | <1 | 46,000 | 46,000 | 100% | PASS | |
| | | 3" DIA | 0,350 | " | | | | | | | | |
| 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

A.N.C.I. Servizi S.r.l.
a socio unico
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CIMAC
Centro Italiano
Materiali di Applicazione
Calzaturiera

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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 0381.73383 - 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

# Dossier d'information type Euro Pharmat

## DISPOSITIF MEDICAL

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CIMAC
Centro Italiano
Materiali di Applicazione
Calzaturiera

ACCREDIA
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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

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

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Materiali di Applicazione
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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