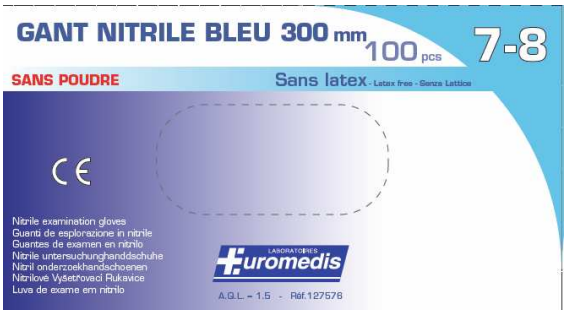
Dossier d'information type Euro Pharmat

DISPOSITIF MEDICAL



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

1. Administrative information concerning the company		***Goes back to update: 22/01/2014*** ***Go back to edition: 22/01/2014***
1.1	**Name:** Laboratories EUROMEDIS	
1.2	**Complete address:** Z.I of Tilery 60290 NEUILLY SOUS CLERMONT	**Such:** +33 344738360 **Fax:** +33 344735732 **e-mail:** euromedis@euromedis.fr **Internet site:** www.euromedis.fr
1.3	**Coordinates of the correspondent matériovigilance:** Mr. Eddie ZERBIB Manager quality	**Such:** +33 344738360 **Fax:** +33 344735732 **e-mail:** eddie.zerbib@euromedis.fr

2. Information on facility or equipment	
2.1	**Name:** d' Europharmat ® nomenclature
2.2	**Trade name:**
	POWDERED BLUE NITRILE GLOVE 300 mm
2.3	**Code nomenclature:** 11882
2.4	**Code PBDA * (ex if applicable TIPS)** :
2.5	**DM class:** Class I **L'applicable EU directive:** 93/42/EC **According to annex No.:** IX Chapter 3 and VII Chapter 3 **Number of the body notified:** CE **Date of first placing on the market in the EU:** 02/2000 **Manufacturer of DM:** Laboratoires EUROMEDIS **The company manufacturer certificate:** ISO 9001: 2008 and ISO 13485: 2012 **Certifying body:** LNE / G - MED **Standards applicable to the medical device:** - Directives 93/42 EC for medical devices EN 455-1/2/4 - medical gloves for single use - Directives 89/686 CE for protection equipment individual EN 374-1/2/3 - protective gloves against chemicals and micro-organisms EN 420 - Gloves of protection General requirements and test methods

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2.6

Description of the device (with photo, schema, dimensions, volume,...) : can be connected to the point 8 : on sheet.

This glove is especially recommended to people who cannot use latex gloves. Its resistance to the many products chemical and puncture in comparison to natural rubber latex him many advantages in its daily use.

Ambidextrous examination glove is available in 4 sizes 6/7, 7/8, 8/9 and XL

Single use: Yes
Color: Blue
Texture: rough distal end
Shape: Ambidextrous
Edge: Rolled

Food: see Chapter 2.9
Color-coded packaging: Yes, see table of dimensions
Origin: South-East Asia
Kit: not

Size of the device:

Size		Length in mm Mini (±5 mm)	Perimeter of the Palm in mm	Thickness in mm (0.01)		
				Cuff	Palm	Finger
T 5/6	XS	300	≤80	0.09	0.10	0.09
T 6/7	S	300	80±10	0.09	0.10	0.09
T 7/8	M	300	95±10	0.09	0.10	0.09
T 8/9	L	300	110±10	0.09	0.10	0.09
T 9/10	XL	300	≥110	0.09	0.10	0.09

2.7

References catalog :

For each reference specify :

REFERENCE:

Packaging / packaging

UCD (Control unit): box
CDT (Multiple of l'UCD): quantity per carton
QML (Minimum delivery quantity): carton

Product specification	Reference	Units / box	Boxes / carton	Units / carton
T 6/7	127575	100	10	1000
T 7/8	127576	100	10	1000
T 8/9	127577	100	10	1000
T 9/10	127578	100	10	1000

2.8

Composition of the device and accessories:

LaTeX: Non curing Agent: Yes
Presence of DEHP: Non
Product from animal or biological: Non

- Nitrile Butadiene elastomer
- Zinc oxide
- Sulfide
- Titanium dioxide
- Zinc Dibuthyl Dithiocarbamate (accelerator)
- Potassium hydroxide
- Calcium nitrate

Devices and accessories related to list. NA

Characteristics of the reference:

Standard	Test	Results
EN 455-1	watertightness	Level inspection 1: AQL = 1.5
EN 455-2	Minimum breaking force	
	-Before aging accelerated	6.2 ≥ N
	-After aging accelerated:	≥ 6.0 N
EN 455-3	Residual powder rate	<0.1 mg/glove
EN 455-3	Levels of protein	<10µg/g
455 - 4	Determination of shelf life	5 years
EN 374-1	Terminology	Conform
EN 374-2	The water leak test	Conform
EN 374-2	Air leakage testing	Conform
EN 374-3	(L) Acide 96%	> 30 min index 2
	(K) Hydroxyde sodium 40%:	> 30 min index 2
	(G) Diethylamine	> 30 min index 2
IN 420	Size and dimension	OK
ISO 10993-1	Cytotoxicity	Tested
	Sensibility	Tested
	Irritation	Tested
ASTM D 6978-05	Test of chemotherapy drugs	Tested
ASTM F 1671-07	Viral penetration	Tested
Alimentarity		
Regulation No. 10/2011 Regulation 1935/2004/EC	-Migration test	Any type of food

Labelling: Labelling complies with directive 93/42 EC.

2.9 **Domain - Indications:**
Domain d'use: Medical and industrial
Indications:NA

3 Sterilization process:

Sterile DM: Non

4 Conservation and storage requirements

Normal conditions of preservation & storage: should not be exposed to moisture and sunlight
Special precautions: single use
Duration of validity of the product: 5 years
Presence d'indicators of temperature s'it is necessary:

5 Operating safety

5.1 **Technical security:** Norm EN 455-1/2/3, 374-1/2/3 and 420

5.2 **Biological safety:** NA

6 Tips for using

6.1 **Instructions:** NA

6.2 **Indications:** (destination CE marking)
Medical examination-Protection of the patient and the user during care

6.3 **Precautions employment':** Do not open with an object cutting

6.4 **Counter - Indications:** NA

7. Additional information on the product

	Bibliography, report d'clinical trials, or d'pharmaco-economic studies, improvement of the service provided: specific recommendations of 'use (support restrictions, technical platform, the operator qualification, etc.)...: All information is contained in the technical file
8 List of annexes to the folder (if applicable)	
	- Labelling and traceability label (is applicable) Labelling complies with directive