
SKYMED
Nitrille Gloves
Nitrille Gloves
Powder Free
Non- Sterile
S
Vinyl x 150
CE FDA
SKYMED
Nitrille Gloves
Nitrille Gloves
Powder Free
Non- Sterile
S
Vinyl x 150
These essential disposable gloves
manufactured in blue vinyl offer
protection in lower risk environments f
rom contaminants, dirt and irritants.
CE FDA
Thailand BEST
SKYMED

SKYMED®

SKYMED®

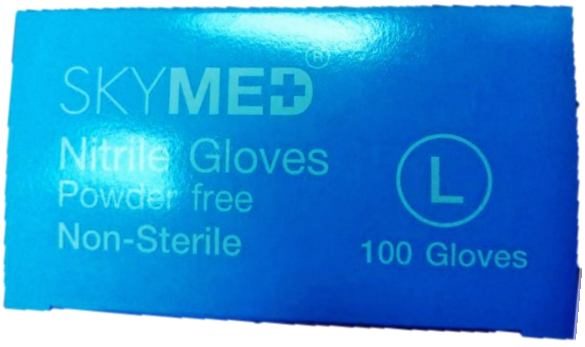
Sufficiency Economy City Co., Ltd.
joint cooperation with
Phoenix Rubber Products Co., Ltd.

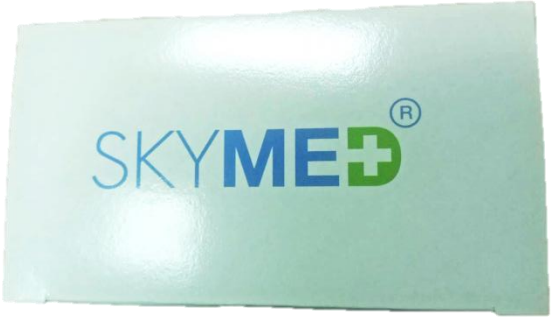
SKYMED® Blue Nitrile Powder Free Non-Sterile


SKYMED
Nitrile Gloves
Powder free
Non-Sterile
L
100 Gloves
CE


SKYMED
Average Thickness
100 Gloves per Box
Powder Free & 100%
Not Medical Grade
Ambidextrous & Easy Dispense Box


SKYMED
Protection Gloves
Nitrile Gloves
Powder free
Non-Sterile
Sufficiency Economy City Co., Ltd
Head Office
152 Moo 12, Tha Kwian, Watthana
Nakhon, Sa Kaeo, THAILAND 27160
Bangkok Office
99/4 Ladprao 8, Chomphon, Chatuchak
Bangkok, THAILAND 10900
Factory
55/5 Moo1, Ban Ko, Mueang,
Samut Sakhon, THAILAND 74000
www.sufficiencyeconomycity.com
Tel: +66 89 1155551
Email: sufficiency.economy.city@gmail.com
Please Contact Our Representatives
100 Gloves / Per Box
FDA CE


SKYMED
Nitrile Gloves
Powder free
Non-Sterile
L
100 Gloves


SKYMED

Easy Donning, Excellent Comfort, High Quality, High Resistance to Tearing, Low Protein, Fit with Hands, Complying with ISO 9001:2015, FDA 510K, ASTM-D-3578, EN455 PART 1-3, CE

SKYMED®

Product Properties : Nitrile Powder Free Non-Sterile

Type : Powder-Free
Specification : Non-Sterile, Ambidextrous, Disposable
Cuff : Beaded
Surface : Smooth/Textured
Color : Blue
Main Material : Natural Concentrated Latex
Parameter
1. Silicone-Free
2. Chloride Max. 0.85 mg./g.
3. Amide Non Detectable
4. DOP Non Detectable

Type	Protein Content	Powder control
Powder-Free	<= 50 µg/g	<= 2 mg/glove
Tensile	**ASTM**	**EN455**
Before Aging	>= 14 Mpa	-
After Aging	>= 14 Mpa	-
Elongation	**ASTM**	**EN455**
Before Aging	>= 400%	-
After Aging	>= 350%	-

Dimensions	XS	S	M	L	XL
Width (mm.)	74-78	82-85	92-95	103-106	112-115
Length (mm.)	ASTM	Minimum for all size 230 mm.			
	EN455	Minimum for all size 240 mm.			
Thickness (mm.)	Cuff	0.05-0.09 mm.			
	Palm	0.07-0.11 mm.			
	Finger	0.08-0.12 mm.			

Quality : Conformed to ASTM - D3578 - 01 ae2 and FDA 510 (K)
Conformed to EN455 part 1-3 and CE

Brand : SKYMED®
Standard Packing :
100 Pieces / Dispenser Box
10 Dispenser Boxes / Carton
1,200 Cartons / 20'FCL
2,400 Cartons / 40'FCL

Declaration of Conformity

for the Self-Certification of Class 1 Medical Devices (Examination Gloves)

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Examination Gloves
Legal Manufacturer: (Name on Label)	Phoenix Rubber Products Co. Ltd., 1313/2-3 Moo5, Tambon Samrongnua, District Mueang, Samutprakarn 10270, Thailand.
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	For the covering of hands of medical staff during examination procedures involving patient body surfaces and patient body orifices.
MD Directive Classification:	Class I
Notified Body:	Not Applicable for Class I
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr.,Tower Street,Swatar, BKR 4013Malta.
Medical Device Directive Assessment Route:	Self-certification by Medical Device Directive Annex VII; EC Declaration of Conformity and Article 14; Registration of persons responsible for placing devices on the market.

Name Chalongkwan Wongsasuthikul **Position** Marketing & Sales Manager

Signed _____ **Date** 14/03/2019

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's nameregardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

SKYMED®

2020

CERTIFICATE OF REGISTRATION

This certifies that:

PHOENIX RUBBER PRODUCTS CO., LTD.
1/7 Bangna Thani BLDG, 3rd FL Room 3B Soi Bangna-Trad 34
Bagna Tai, Bangkok , THAILAND 10260

is registered with the U.S. Food and Drug Administration for FY 2020 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Registration:	**3005688346**
DUNS No.:	**67-169-5763**
Device Classification Name:	**LATEX PATIENT EXAMINATION GLOVE**
Product Code:	**LYY**
Regulation Number:	**880.6250**
Official Correspondent and U.S. Agent:	Registrar Corp 144 Research Drive, Hampton, Virginia, 23666, USA Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Registrar Corp assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."

The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.

Registrar Corp
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Telephone: +1-757-224-0177 • Fax: +1-757-224-0179
info@registrarcorp.com • www.registrarcorp.com

David Lennarz
Executive Director
Registrar Corp
Dated: January 20, 2020

Phoenix Rubber Products Company Limited Version: 1.0

EU Declaration of Conformity Date: 14/03/2019

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
XS,S,M,L,XL	Rubber latex – natural colour	56286
XS,S,M,L,XL	Rubber latex – white colour	56286
XS,S,M,L,XL	Nitrile – blue colour	56286

Size definition used in table:

XS – Extra small S – Small M – Medium L – Large XL – Extra Large

Packaging of all gloves; 100 units per disperser box and 10 disperser boxes per skipper carton

NOTE: Other configurations of similar products may be made available from time to time and this certificate shall cover those also.

Version History

Version	Compiled by	Date	Description
1.0	Phoenix Rubber Products Co. Ltd.,	14/03/2019	First issue

SKYMED®

Certificate of Registration

In accordance with European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states.

We hereby declare that:

- An examination has been made of this organisation's Declaration of Conformity(s) and where appropriate Notified Body certification(s) exist.
- The EU Authorised Representative contract has been fulfilled.
- Device registrations for the medical devices mentioned within this certificate have duly been completed with an EU Competent Authority.

Therefore, these devices have met the requirements of the council directive and the CE mark may be applied to the products listed below.

Certificate No: CE/THA/1999/09/03	Issue Date: 01st April 2020	Expiry Date: * 31st March 2021

**Please note, due to the implementation date of the new medical device regulation (EU 2017/745) this certificate is subject to a review of the client's technical documentation before the 26th May 2020, whereupon a new Certificate of Registration is issued once compliance to the medical device regulation has been achieved.*

Legal Manufacturer	EU Authorised Representative (EC REP)
Phoenix Rubber Products Co Ltd 1313/2-3, Moo 5, Tambon Samrongnua, District Mueang, Samutprakarn 10270, Thailand	Advena Limited, Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013 Malta.

Product Details, Names or Trade Names	MCCAA Device Registration Reference(s)
Examination Gloves	DVC-MT-20-02-000061

Competent Authority
Malta Competition and Consumer Affairs Authority (MCCAA) Mizzi House, National Road, Blata l-Bajda, HMR 9010 Malta. Tel: +356 2395 2000 Email: info@mccaa.org.mt

This certificate is issued by:	Authorised Signature:
Advena Limited Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013. Malta. Tel: +44 1926 800153 Email: info@advenamedical.com Registered in Malta No. C 76865	Anthony Kirby – Managing Director (Malta)

This certificate is subject to the organisation maintaining their documentation in compliance with the directive stated in this certificate.

Certificate TH20/13101

The management system of

Mercator Medical (Thailand) Ltd.

88/8, 88/9 Moo 12, Tambon Kampaengphet, Amphur Rattaphum,
Songkhla, 90180, Thailand

has been assessed and certified as meeting the requirements of

Good Manufacturing Practice

Codex Alimentarius Commission,
Recommended International Code of Practices,
General Principles of Food Hygiene, CAC/RCP 1-1969, Rev. 4 (2003)

For the following activities

The Manufacture of Powder Free Natural Latex and Nitrile Gloves for Food Contact Application

Further clarifications regarding the scope of this certificate and the applicability of GMP requirements may be obtained by consulting the organization

This certificate is valid from 16 March 2020 until 16 March 2023 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 27 February 2023
Issue 1. Certified since 16 March 2020

Authorised by

SGS (Thailand) Limited
100 Nanglinchee Road, Chongnonsee, Yannawa, Bangkok 10120, Thailand
t +66 (0)2 678 18 13-43 f +66 (0)2 678 06 20 www.sgs.com

Certificate TH10/4860

The management system of

Mercator Medical (Thailand) Ltd.

88/8, 88/9 Moo 12, Tambon Kampaengphet,
Amphur Rattaphum, Songkhla 90180, Thailand

has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

Manufacture and distribution of industrial gloves
Manufacture and distribution of non-sterile powdered natural latex examination gloves
Manufacture and distribution of non-sterile powder free natural latex examination gloves
Manufacture and distribution of non-sterile nitrile examination gloves

This certificate is valid from 25 June 2019 until 25 June 2022 and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date.
Issue 7. Certified since 25 June 2010

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 9001 2015 0618

Food and Drug Administration

Ministry of Public Health, Thailand

CERTIFICATE OF FREE SALE

Ref.No. 1-1-03-02-17-000425

July 20, 2017

It is hereby certified that **Mercator Medical (Thailand), Ltd., 88/8 Moo 12 Tambon Kampaengphet, Amphur Rattaphum, Songkhla 90180, Thailand** does manufacture the following medical device pursuant to the Medical Devices Act 2008.

The following products may be sold in Thailand and exported without restriction.

Name of Products : **Latex Powdered Examination Gloves**
Latex Powder Free Examination Gloves
Nitrile Examination Gloves

This certificate is issued upon the request of Mercator Medical (Thailand), Ltd., Thailand.

Valid until 19 July 2019

(Mrs. Korrapat Trisarnsri)
Senior Pharmacist
Acting Director of Medical Device Control Division
For Secretary-General Food and Drug Administration

88/24 Tivanon Road, Nonthaburi 11000, Thailand
Tel. (662) 590-7149, Fax. (662) 591-8445

สำนักงานคณะกรรมการอาหารและยา

Food and Drug Administration

GMP CERTIFICATE

Ref. No. 1-1-04-02-19-00079

Valid until : 18 November 2022

It is hereby certified that

Mercator Medical (Thailand) Ltd.

88/8, 88/9, Moo 12, Tambon Kampaengphet,
Amphur Rattaphum, Songkhla 90180, THAILAND

is found to conform to the current Medical Device Good Manufacturing Practice 2005 laid down in accordance with the International Standard Requirements.

Scope : Manufacturing of non-sterile Natural Rubber Latex and Synthetic Latex Examination Gloves

Issued on: 3 December 2019

.....

(Mr Surachai Tangwiwat)
Deputy Secretary-General
For Secretary-General
Food and Drug Administration

Valid From : 19 November 2019

Medical Device Group 66.00 2590 7280,66 2590 7284 Fax.66 2590 7280

FOOD CONTACT CENTER

TestReport n°	18-FC00335	Date:	25/01/2019

Cliente / *Customer*	Mercator Medical Thailand Ltd.
Indirizzo / *Address*	88/8 Moo12, Tambon Kamphaeng Phet, Rattaphum District, Songkhla 90180, Thailandia
Descrizione Campione / *Sample Description*	Nitrile Powder Free Blue Glove Size M, 1 Box
Campionamento / *Sampling*	A cura del cliente / By Customer
Data di arrivo / *Arrival Date*	17/12/2018
Data di inizio prove / *Start Test Date*	07/01/2019
Data di fine prove / *End Test Date*	25/01/2019
Ref. Standard/Method:	DM 21.03.73, Arrêté du 9/11/1994, Note d'information n°2004-64

Autorizzato da
Authorized By

Direttore Tecnico
Technical Manager

SAMPLE/ATTACHMENT PICTURE

********** End of Report **********

This Test Report cancels and supersedes the Test Report No.4398439 Dated 21-Oct-2019 issued by SGS (Thailand) Ltd.

"Any holder of this document is advised that should client or third party information be supplied with respect to the goods or sample, SGS may, at its discretion, attached or indicate such information to the report but SGS makes no warranties or accepts no liable for the veracity or lack thereof of such Information."

TEST RESULTS

Commission Directive 93/11/EEC and Council of Europe Resolution AP (2004) 4

a) Rubber – Overall migration

Method : With reference to EN 1186-1:2002 for selection of conditions and test methods; (1st Migration)
EN 1186-5:2002 aqueous food simulants by cell method.

Simulant Used	Test Condition	Result (1) (mg/dm2)	Reporting Limit (mg/dm2)	Permissible Limit (mg/dm2)
3% Acetic Acid (W/V) Aqueous Solution	2 hours at 40 degree C	ND	3.0	10
Comment	--	PASS	--	--

Sample Description :
1. Blue rubber (outside)

Note :
1. mg/dm2 = milligram per square decimeter
2. degree C = degree Celsius
3. ND = Not Detected
4. Permissible Limit is according to Council of Europe Resolution AP (2004) 4.

Remark :
1. Analytical tolerance of aqueous simulants is 1mg/dm2 or 6mg/kg
2. Test condition & simulant were specified by client.

This Test Report cancels and supersedes the Test Report No.4398439 Dated 21-Oct-2019 issued by SGS (Thailand) Ltd.

4104436

Test Report No. 4402723 Date : 25-Oct-2019

Client : Mercator Medical (Thailand) Ltd.
88/8, M 12,
T. Kampaengphet, A. Rattaphum, Songkhla 90180 Thailand

The following sample(s) was/were submitted and identified by client as:

Sample Name	: Glove
Sample Description	: Powder Free Nitrile Blue Examination Glove
Batch/Lot No.	: PC000420419
Color	: Blue
Manufacturer/Vendor	: Mercator Medical (Thailand) Ltd.
Country of Origin	: Thailand

The following sample(s) was/were identified by SGS as:

SGS Sample No.	: 4557128
Sample Condition	: Sample is contained in a plastic bag.
Quantity Submitted	: 10 pcs

Sample Receiving Date	: 16-Oct-2019
Testing Period	: 16-Oct-2019 to 21-Oct-2019

Test Method & Results : Please refer to next page(s).

Test Requested & Result Summary

Test Requested : Please refer to the result summary (Test parameter(s) was/were selected by client).

Result Summary:

Test Requested	Conclusion
European Commission Directive 93/11/EEC and Council of Europe Resolution AP (2004) 4	--
a) Rubber - Overall Migration	
3% Acetic Acid (W/V) Aqueous Solution	PASS

Remark: Test results in this report are applicable for the item tested and reflects the tested sample as received.

Signed for and on behalf of
SGS (Thailand) Limited

Rutchuporn Moungsom
Laboratory manager - Toy and Hardgood

This Test Report cancels and supersedes the Test Report No.4398439 Dated 21-Oct-2019 issued by SGS (Thailand) Ltd.

"Any holder of this document is advised that should client or third party information be supplied with respect to the goods or sample, SGS may, at its discretion, attached or indicate such information to the report but SGS makes no warranties or accepts no liable for the veracity or lack thereof of such Information."

ESITO D'ESAME/*TEST RESULTS*	RIS	Inc	u.m.	LOQ	LIM	Metodo / *Method*	Inizio *Start*	Fine *End Test*
MIGRAZIONE SPECIFICA di 9 METALLI in ACIDO ACETICO al 3% / *Heavy Metals Specific Migration in ACETIC ACID 3%*						UNI EN 13130-1:2005+ MHTH003rev 0 2016	7/1	9/1
Risultati relativi al terzo attacco / *Third Attack Results*								
Tempo /Time	2.0							
Temperatura / *Temperature*	40		°C					
Alluminio/*Aluminium*	ND		mg/kg	0,01	<1			
Bario/*Barium*	ND		mg/kg	0,01	<1			
Cobalto /*Cobalt*	ND		mg/kg	0,01	<0,05			
Rame/Copper	ND		mg/kg	0,01	<5			
Ferro/*Iron*	ND		mg/kg	0,01	<48			
Litio/*Lithium*	ND		mg/kg	0,01	<0,6			
Manganese	ND		mg/kg	0,01	<0,6			
Nichel/*Nickel*	ND		mg/kg	0,01	<0,1			
Zinco/*Zinc*	ND		mg/kg	0,01	<25			

ESITO D'ESAME/*TEST RESULTS*	RIS	Inc	u.m.	LOQ	LIM	Metodo / *Method*	Inizio *Start*	Fine *End Test*
Formaldehyde migration in AcOH 3%	ND		mg/kg	1	3	EN 13130-23:2004; Arreté du 9/11/1994, annexe IV	7/1	8/1
VOC (volatile substances)	0,3		%	0,1	0,5	EN 12868:1999; Arreté du 9/11/1994, annexe IV	9/1	9/1
N-Nitrosamines [1]	ND		µg/dm²	10	10	EN 12868:1999; Arreté du 9/11/1994, annexe IV	9/1	9/1
Substances N-Nitrosables	ND		µg/dm²	1	1	EN 12868:1999; Arreté du 9/11/1994, annexe IV	9/1	9/1

Note 1: Nitrosamines tested: N-Nitroso-dimethylamine (NDMA), N-Nitroso-diethylamine (NDEA), N-Nitroso-di-n-propylamine (NDPA), N-Nitroso-di-n-butylamine (NDBA), N-Nitroso-morpholine (NMOR), N-Nitroso-piperidine (NPIP), N-Nitroso-pyrrolidine (NPYR), N-nitrosodibenzylamine (NDBzA), N-nitrosodiisononylamine (NDiNA), N-nitroso N-methyl N-phenylamine, N-notroso N-ethyl N-phenylamine (NEPhA)

	ESITO D'ESAME/*TEST RESULTS*							
	RIS	**Inc**	**u.m.**	**LOQ**	**LIM**	**Metodo / *Method***	**Inizio *Start***	**Fine *End Test***
Migrazioni specifiche dei coloranti / Coloring Specific Migration								
Analisi eseguite per riempimento dopo aver rivoltato l'oggetto, chiudendolo alle estremità / *Analysis performed by filling after turning the object over and closing it at the ends*								
Tempo (ore) / *Time (hours)*	2.0							
Temperatura / *Temperature*	40		°C					
Migr. Specifica di coloranti in acido acetico 3% per riempimento / *Colourings Spec. Migr. in Acetic Acid 3% by filling*	99		%		>95	DM n°34 21/03/1973 SO GU n°104 20/04/1973 All IV Sez.7	7/1	7/1
Migr. Specifica di coloranti in etanolo 10% per riempimento / *Colourings Spec. Migr. In Ethanol 10% by filling*	98		%		>95	DM n°34 21/03/1973 SO GU n°104 20/04/1973 All IV Sez.7	7/1	7/1
Migr. Specifica di coloranti in olio di girasole per riempimento / *Colourings Spec. Migr. In Sunflower Oil by filling*	98		%		>95	DM n°34 21/03/1973 SO GU n°104 20/04/1973 All IV Sez.7	7/1	7/1
Migrazioni Specifiche / Specific Migrations								
Migr. Spec. Amm. Aromatiche Prim. in Ac.acetico 3% per riempimento / *Primary aromatic Amines Migr. in Acetic Acid 3% by filling*	ND		mg/kg	0,01	<0,01	§ 64 LFGB, MethodL N°00.00-6	7/1	8/1
Risultati relativi al primo attacco / *First Attack Results*								
Tempo (ore) / *Time (hours)*	2.0							
Temperatura / *Temperature*	40		°C					
Determinazione di Mercaptobenzotiazolo in liquido di cessione H20 / *Determination of Mercaptobenzothiazole in leaching liquid H20*	ND		mg/l	0,03	<0,05	DM 21/03/1973 GU n°104 20/04/1973 All IV Sez 3 P.to 2	7/1	8/1
Determinazione di Ditiocarbammati, tiourami e xantogenati in simulante etanolo 10% / *Determination of Dithiocarbammate, tiourames and xanthogentes in ethanol 10%*	ND		mg/dm^2	0,05	<0,2	Reg UE 10/2011 14/01/2011 GU L12/1 15/01/2011 App V + UNI EN 1186-3:2003	7/1	8/1
Migrazione di Acrilonitrile in Etanolo 10% / *Acrylonitrile migration in Ethanol 10%*	ND		mg/kg	0,01	<0,01	UNI CEN/TS 13130-3	7/1	8/1
Tempo (min) / *Time (min)*	10							
Temperatura / *Temperature*	40		°C					
Determinazione di Perossidi in simulante Isoottano / *Determination of Peroxides in Isooctane simulant*	ND		mg/dm^2	0,01	<0,5	DM 21/03/1973 GU n°104 20/04/1973 All IV Sez 3 P.to 2	7/1	8/1

	ESITO D'ESAME/*TEST RESULTS*							
	RIS	**Inc**	**u.m.**	**LOQ**	**LIM**	**Metodo / *Method***	**Inizio *Start***	**Fine *End Test***
Migrazioni globali / *Overall Migration* s								
Analisi eseguite per riempimento dopo aver rivoltato l'oggetto, chiudendolo alle estremità / *Analysis performed by filling after turning the object over and closing it at the ends*								
Risultati relativi al primo attacco / *First Attack Results*								
Tempo (ore) / *Time (hours)*	2.0							
Temperatura / *Temperature*	40		°C					
Migrazione globale in acido acetico al 3% per riempimento / *Overall Migration in Acetic Acid 3% by filling*	1,2		mg/dm^2	1	<8	Reg UE 10/2011 14/01/2011 GU L12/1 15/01/2011 App V + UNI EN 1186-9:2003	7/1	7/1
Nota: È stato applicato il limite di migrazione globale previsto dal DM 21.03.73 per materiali diversi dalla plastica, che prevede per i simulanti acquosi la tolleranza analitica di 2mg/dm2 /*Note: The global migration limit set by Ministerial Decree 21.03.73 for materials other than plastic has been applied, which provides for analytical tolerance of 2mg / dm2 for aqueous simulants*								
Migrazione globale in etanolo al 10% per riempimento / *Overall Migration in Ethanol 10% by filling*	ND		mg/dm^2	1	<8	Reg UE 10/2011 14/01/2011 GU L12/1 15/01/2011 App V + UNI EN 1186-9:2003	7/1	7/1
Migrazione globale in olio di oliva per riempimento / *Overall Migration in Olive Oil by filling*	3,37		mg/dm^2	1	<8	Reg UE 10/2011 14/01/2011 GU L12/1 15/01/2011 App V + UNI EN 1186-8:2003	7/1	7/1
Risultati relativi al terzo attacco / *Third Attack Results*								
Tempo (ore) / *Time (hours)*	2.0							
Temperatura / *Temperature*	40		°C					
Migrazione globale in acido acetico al 3% per riempimento / *Overall Migration in Acetic Acid 3% by filling*	0,8		mg/dm^2	1	<8	Reg UE 10/2011 14/01/2011 GU L12/1 15/01/2011 App V + UNI EN 1186-9:2003	8/1	8/1
Migrazione globale in etanolo al 10% per riempimento / *Overall Migration in Ethanol 10% by filling*	ND		mg/dm^2	1	<8	Reg UE 10/2011 14/01/2011 GU L12/1 15/01/2011 App V + UNI EN 1186-9:2003	8/1	8/1
Migrazione globale in olio di oliva per riempimento / *Overall Migration in Olive Oil by filling*	ND		mg/dm^2	1	<8	Reg UE 10/2011 14/01/2011 GU L12/1 15/01/2011 App V + UNI EN 1186-8:2003	8/1	8/1

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Per i parametri chimici i valori di incertezza estesa sono riferiti ad un intervallo di confidenza del 95%. Fattore di copertura k=2.

Chemical determinations: expanded uncertainty is referred to 95% confidence level. Coverage factor k=2.

Il limite di determinazione (LOD) risulta uguale a 1/10LOQ*3

*The limit of determination (LOD) results as 1/10LOQ*3*

N.D. = inferiore a LOQ (limite di quantificazione)

N.D= less than LOQ (limit of quantification)

I risultati riportati sono riferiti al solo campione sottoposto a prova.

The reported results only refer to the tested sample.

u.m. = unità di misura; Inc = Incertezza; RIS= Risultato; LIM=limite
u.m. = unit of measurement; unc = uncertainty; R= Result; LIM=Limit