

CCIR ASIA PACIFIC LIMITED

Unit 20, 1/F, Office Block Two,
96 Siena Avenue, Discovery Bay North,
Hong Kong



DECLARATION OF CONFORMITY
REGULATION (EU) No 10/2011

MANUFACTURER

CCIR ASIA PACIFIC LIMITED, Unit 20, 1/F, Office Block Two, 96
Siena Avenue, Discovery Bay North, Hong Kong, CHINA

This certificate is valid for the following product:

VINYL EXAMINATION GLOVES - NO STERILE - POWDER FREE

We hereby confirm that the products with CE marking above
mentioned comply with:

The applicable provisions of Regulation (UE) No 10/2011 of 14
January 2011 Annex III and Annex V for selection of condition
and EN 1186-1:2002 for selection of test methods ; or EN1186-
9:2002 aqueous food simulants by article filling methods and
are subject to the test report No CANHG2000727801.



Quality Manager
Hong Kong, January 7th, 2021
Valid until January 7th, 2025

CCIR ASIA PACIFIC LIMITED

Unit 20, 1/F, Office Block Two,
96 Siena Avenue, Discovery Bay North,
Hong Kong



**DECLARATION OF CONFORMITY
MEDICAL DEVICE DIRECTIVE 93/42/EEC
REGULATION (EU) 2016/425 FOR PERSONAL PROTECTIVE EQUIPMENT**

MANUFACTURER

CCIR ASIA PACIFIC LIMITED, Unit 20, 1/F, Office Block Two, 96
Siena Avenue, Discovery Bay North, Hong Kong, CHINA

EU REPRESENTATIVE

MSC TEST SERVIPONS, S.L., Pujada Parc. 7-B, 08692 PUIG REIG
(BARCELONA), SPAIN

This certificate is valid for the following product:

VINYL EXAMINATION GLOVES - NO STERILE -POWDER FREE

Classification:

Class I according to Directive of Medical Device 93/42/EEC
Category III according to PPE Regulation (EU) 2016/425

We hereby confirm under our sole responsibility that the
products with CE marking above mentioned comply with:

- To the essential requirements (Annex I) of the Directive
93/42/EEC modified by the Directive 2007/47/CE for
medical devices, and are subject to the test certificate
IN-03241/2014-B-4
Applied standards: UNE-EN 455-1:2001, UNE-EN 455-
2:2010+A1:2011 and UNE-EN 455-3:2007
- The applicable provisions of Regulation (UE) 2016/425 on
Personal Protective Equipment, and are subject to the
test certificate IN-01657-2013-OC-CE-E-1 and its update
IN-01657-2013-OC-CE-E-2, and EU Type Examination
Certificate (Module B) IN-00575/2019-OC-UE-E
Applied standards: EN 420:2003+A1:2009, EN ISO 374-1:2016
(Type C), EN 374-2/03, EN 374-3/03+AC/06 and EN 374-4:2013

The certificates have been issued by
LEITAT - ACONDICIONAMIENTO TARRASENSE
C/ de la Innovació, 2, 08225 TERRASSA (BARCELONA) - SPAIN



Quality Manager
Hong Kong, May 2nd, 2019
Valid until May 2nd, 2024

The tests identified with (*) are not included within the ENAC scope of accreditation.

CCIR ASIA PACIFIC LIMITED

Suite 1803, 18 Floor, Beautiful Group Tower
77 Connaught Road Central
Hong Kong

INFORME TÉCNICO / TECHNICAL REPORT

Informe Nº / Report Nº: IN-03241/2014-B-4
Páginas / Pages: 7

MUESTRA PRESENTADA / PRESENTED SAMPLE

Descripción muestra / Sample description:

Unos guantes referenciados como: / Gloves referenced as: **“GUANTES DE EXPLORACIÓN/PROCEDIMIENTO DE VINILO - EXAMINATION / PROCEDURE VINYL GLOVES”**

Fecha de presentación / Presentation date: 22/12/14

DETERMINACIONES SOLICITADAS / REQUESTED TESTS

Ensayos según Norma UNE – EN 455 – 01 – Guantes médicos para un solo uso determinación de ausencia de agujeros. / Tests according to standard UNE – EN 455 – 01 – Medical gloves for single use. Medical gloves for single freedom from holes.

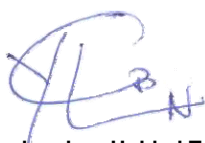
- DETERMINACIÓN DE LA AUSENCIA DE AGUJEROS / DETERMINATION OF FREEDOM FROM HOLES. (*)
Norma / Standard UNE – EN 455-1:2001.

Ensayos según Norma UNE – EN 455-2:2010+A2:2013. Guantes médicos para un solo uso - Determinación de las propiedades físicas - / Tests according to standard UNE – EN 455-2:2010+A1 2011. Medical gloves for single use – Requirements and testing for physical properties

- GUANTES MÉDICOS PARA UN SOLO USO. REQUISITOS Y ENSAYOS PARA DETERMINAR LAS DIMENSIONES DE UN GUANTE. / MEDICAL GLOVES FOR SINGLE USE. REQUIREMENTS AND TESTS TO DETERMINE THE DIMENSIONS OF A GLOVE (*)
Norma / Standard UNE – EN 455-2:2010+A2:2013. Apartado / Section 4.

- GUANTES MÉDICOS PARA UN SOLO USO. RESISTENCIA A LA TRACCIÓN ANTES Y DESPUÉS DEL ENVEJECIMIENTO ACELERADO / *MEDICAL GLOVES FOR SINGLE USE. TENSILE STRENGTH BEFORE AND AFTER AGING (*)*
Norma / *Standard* UNE – EN 455-2:2010+A2:2013. Apartado / *Section* 5.2 – 5.3.

Fechas de realización / Performance dates: del / *from* 22/12/14 al / *to* 16/01/15



Coordinadora Unidad Textil
Textile Unit Coordinator
Yolanda Cabrejas



Responsable Técnico Textil
Textile Technical Manager
Miquel Morera

Terrassa, 16 de Enero de 2015
Terrassa, January 16th, 2015

**DETERMINACIÓN DE LA AUSENCIA DE AGUJEROS /
DETERMINATION OF FREEDOM FROM HOLES.**

Norma / Standard UNE EN 455-1:2001.

Concepto / Scope : Este ensayo tiene por objeto la determinación de la ausencia de agujeros, mediante el ensayo de estanquidad, en los guantes médicos de un solo uso. /*This test is intended to determine the absence of holes, by means of the watertightness test on medical gloves for single use.*

Equipo utilizado / Equipment used: Cubeta de recogida de agua, cronometro / *Water collecting tray, chronometer*

Acondicionamiento de las probetas / Conditioning of the specimens: 24 h - 20°C ± 2°C y/and 65% ± 4% h.r./r.h

Condiciones de ensayo / Test conditions:

Nº de probetas ensayadas / *No. of specimens tested:* 5

Volumen de agua a aplicar/ *Quantity of water to be applied:* 1000 ± 50 ml.

Temperatura del agua / *Water temperature:* 15 – 35 °C.

Sistema de valoración / *Evaluation system:*

- Inspección inmediata después de la aplicación del agua / *Immediate inspection after application of water.*
- Inspección después de 2 – 3 min. de la aplicación del agua/ *Inspection 2 - 3 min. after application of water.*

Tratamiento previo / *Previous treatment:* Nulo / *Null*

Resultados obtenidos / Results obtained:

**Valoración inmediata, después de la aplicación del agua./
Immediate evaluation, after application of water**

CUMPLE / FULFILL

**Valoración después de 2 – 3 min. de la aplicación del agua/
Evaluation 2 - 3 min. after application of water**

CUMPLE / FULFILL

**DETERMINACIÓN DE LAS DIMENSIONES DE UN GUANTE./
DETERMINATION OF DIMENSIONS OF A GLOVE**

Norma / Standard UNE – EN 455-2:2010+A2:2013. Apartado / Section 4

Concepto / Scope: Este ensayo tiene por objeto la determinación de las dimensiones, la longitud y la anchura, en los guantes médicos de un solo uso./ *This test is intended to determine the dimensions, length and width of medical gloves for single use.*

Equipo utilizado / Equipment used: Regla / Ruler.

Acondicionamiento de las probetas / Conditioning of the specimens: 24 h - 20°C ± 2°C y/and 65% ± 4% h.r./r.h

Condiciones de ensayo / Test conditions:

Número de probetas ensayadas/ *No. of specimens tested:* 13

Tomar todas las medidas eliminando las arrugas y los pliegues sin estirar el guante /*Take all the measures eliminating the wrinkles and the folds without stretching the glove.*

Tratamiento previo / *Previous treatment:* Nulo/Null

Resultados obtenidos / Results obtained:

Descripción del guante / Description of the glove	Guantes de exploración – procedimiento / Testing gloves - procedure
Talla especificada por el cliente / Size specified by the client	M
Mediana de la longitud del guante/ Median of the length of the glove (mm)	247.0
Mediana de la anchura del guante/ Median of the width of the glove (mm)	96.0

**RESISTENCIA A LA TRACCIÓN ANTES Y DESPUÉS DEL ENVEJECIMIENTO ACELERADO /
TENSILE STRENGTH BEFORE AND AFTER AGING**

Norma / Standard UNE – EN 455-2:2010+A2:2013. Apartado / Section 5.2 – 5.3.

Concepto / Scope: Este ensayo tiene por objeto la determinación de la fuerza en el punto de rotura antes del envejecimiento acelerado de los guantes. / *This test is intended to determine strength in the breaking point before and after aging of the gloves.*

Equipo utilizado / Equipment used: Dinamómetro de gradiente constante de alargamiento (VCA) INSTRON (Clase 0.5) / *Constant elongation gradient dynamometer (VCA) – INSTRON (Class 0.5)*

Acondicionamiento de las probetas: Mínimo 16 horas a 23°C ± 2°C y 50 % ± 4 % h.r. / *At least 16 hours at 23°C ± 2°C and 50 % ± 4 % RH.*

Condiciones de ensayo / Test conditions:

Atmósfera de ensayo / <i>Test atmosphere:</i> 20°C ± 2°C - 65% ± 4% h.r.
Tipo de mordazas / <i>Type of jaws:</i> Neumáticas / <i>Pneumatic</i>
Tipo de pinzas / <i>Type of nippers:</i> Planas / <i>Flat</i>
Velocidad de ensayo / <i>Test speed:</i> 500 mm/min.
Distancia entre pinzas / <i>Distance between nippers:</i> 50 mm.
Forma de la probeta/ <i>Shape of the specimen:</i> pesa de gimnasia / <i>weight of gymnastics</i>
Número de probetas ensayadas / <i>Number of specimens tested:</i> 12
Tratamiento previo / <i>Previous treatment:</i>
- Original / <i>Original:</i> Nulo / <i>Null</i>
- Envejecido – 7 días a 70°C ± 2°C según norma ISO 188 / <i>Aged - 7 days at 70°C ± 2°C according to ISO 188 (con el envase / with packaging)</i>

Resultados obtenidos / Results obtained:

	Original / <i>Original</i>	Envejecido / <i>Aged</i>
Espesor en la zona del dedo corazón según norma / <i>Thickness in the zone of the middle finger (t_f) according to Standard ISO 23529:2004 (mm)</i>	0.13	0.09
Espesor en la zona de la palma del guante según norma / <i>Thickness in the zone of the palm of the glove (t_x) according to Standard ISO 23529:2004 (mm)</i>	0.08	0.08
Relación entre / <i>Relation between t_f / t_x ⁽¹⁾</i>	1.64	1.09
Factor de corrección aplicado / <i>Applied correction factor</i>	--	--
Fuerza a la rotura aplicando la corrección / <i>Breaking strength applying correction (N)</i>	--	--
Fuerza a la rotura / <i>Breaking strength (N)</i>	4.08	3.98
Mediana fuerza a la rotura / <i>Median Breaking strength (N)</i>	4.06	3.93
C.V. (%)	4.33	8.09

(1 kg = 9,81 N)

⁽¹⁾ Si (t_f/t_x ≥ 0.9) no se debe aplicar el factor de corrección. Si (t_f/t_x < 0.9) se corrige el valor medido multiplicando la fuerza medida por el punto de rotura por el factor de t_f/t_x. / *If (t_f/t_x = 0.9) correction factor must not be applied. If (t_f/t_x < 0.9) the measured value is corrected by multiplying the strength value by the breaking point by the factor of t_f/t_x.*

UNE EN 455

“GUANTES MÉDICOS PARA UN SOLO USO” “MEDICAL GLOVES FOR SINGLE USE”

ENSAYO / TEST	APARTADO NORMATIVA / STANDARD CLAUSE	METODO DE ENSAYO / TEST METHOD	RESULTADOS / RESULTS	REQUERIMIENTO MÍNIMO / MINIMUM REQUIREMENT
UNE EN 455-1:2001 REQUISITOS Y ENSAYOS PARA DETERMINAR LA AUSENCIA DE AGUJEROS / REQUIREMENTS AND TESTING FOR ABSENCE FROM HOLES				
ESTANQUEIDAD AL AGUA / DOWN PROOF PROPERTIES TO WATER	5.1	EN 455-1	C	Ausencia de agujeros Freedom from holes
UNE EN 455-2:2010 +A1:2011 REQUISITOS Y ENSAYOS PARA DETERMINAR LAS PROPIEDADES FÍSICAS / REQUIREMENTS AND TESTING FOR PHYSICAL PROPERTIES				
DIMENSIONES – LONGITUD DIMENSIONS / LENGTH	4.2	EN 455-2	C	VER TABLA / SEE TABLE Nº 1
DIMENSIONES – ANCHURA DIMENSIONS / WIDTH	4.3	EN 455-2	C	VER TABLA / SEE TABLE Nº 1
RESISTENCIA A LA TRACCION: ORIGINAL / TENSILE STRENGTH: ORIGINAL	5.2	EN 455-2	C	VER TABLA / SEE TABLE Nº 3
RESISTENCIA A LA TRACCION: DESPUÉS ENVEJECIMIENTO ACCELERADO / TENSILE STRENGTH: AFTER AGING	5.3	EN 455-2	C	

C : Conforme
C : Conforms

NC : No Conforme
NC : Doesn't conform

NA : No Aplicable
NA : Not applicable

NS : No solicitado
NS : Not request

**Tabla nº 1
(Guantes quirúrgicos /Surgical gloves)**

Tamaño / Size	Mediana de la longitud / Median of the length (mm)	Mediana de la anchura / Median of the width (mm)
5	≥250	67±4
5 ^{1/2}	≥250	72±4
6	≥260	77±5
6 ^{1/2}	≥260	83±5
7	≥270	89±5
7 ^{1/2}	≥270	95±5
8	≥270	102±6
8 ^{1/2}	≥280	108±6
9	≥280	114±6
9 ^{1/2}	≥280	121±6

**Norma UNE – EN 455-2:2010+A2:2013– Tabla nº 2
(Dimensiones de los guantes de exploración/procedimiento / Dimensions of examination/procedure gloves)**

Tamaño / Size	Mediana de la longitud / Median of the length (mm)	Mediana de la anchura / Median of the width (mm)
Extra pequeño/ Small Extra	≥ 240	≤80
Pequeño /Small		80±10
Medio /Medium		95±10
Grande /Large		110±10
Extra grande/ Extra large		≥110

Tabla Nº 3.					
Valores medios de la fuerza en el punto de rotura /					
Average values of strength in the breaking point					
	Guantes quirúrgicos /		Guantes de exploración – procedimiento /		
	Surgical gloves (N)		Examination-procedure gloves (N)		
	A)	B)	C)	D)	E)
Ensayo durante toda la vida útil de acuerdo con el apartado 5.2 (originales) y ensayado dentro de los 12 meses de fabricación según el apartado 5.3 (envejecimiento) / <i>Test during the whole usefull life of agreement with point (original) 5.2 and tested in 12 months of manufacture according to point 5.3 (aging)</i>	≥ 9	≥ 9	≥ 6	≥ 6	≥ 3.6
<p>A) Requisitos para guantes hechos de látex de caucho natural / <i>Requirements for made gloves of latex of natural rubber.</i></p> <p>B) Requisitos para guantes hechos de otros materiales elastoméricos, por ejemplo, policloropreno, poliisopreno sintético, nitrilo, copolímeros en bloque de estireno, poliuretano. / <i>Requirements for made gloves of other elastomeric materials, for example, policloropreno, synthetic polyisoprene, nitrile, copolymers in block of styrene, polyurethane.</i></p> <p>C) Requisitos para guantes hechos de látex y de materiales elastoméricos; excepto nitrilo, por ejemplo, látex de caucho natural policloropreno, poliisopreno sintético, copolímeros en bloque de estireno, poliuretano / <i>Requirements for made gloves of latex and elastomeric materials; except nitrile, for example, latex of natural rubber policloropreno, synthetic polyisoprene, copolymers in block of styrene, polyurethane.</i></p> <p>D) Requisitos para guantes hechos de Nitrilo / <i>Requirements for made gloves of Nitrile</i></p> <p>E) Requisitos para guantes hechos de otros materiales termoplásticos (por ejemplo, cloruro de polivinilo, polietileno) / <i>Requirements for made gloves of other thermoplastic materials (for example, polyvinyl chloride, polyethylene)</i></p>					



Test Report

No. CANHG2000727801

Date: 15 Jan 2020

Page 1 of 3

CCIR ASIA PACIFIC LIMITED

UNIT 20, 1/F, OFFICE BLOCK TWO, 96 SIENA AVENUE, DISCOVERY BAY NORTH HONG KONG

The following sample(s) was/were submitted and identified on behalf of the clients as : VINYL EXAMINATION GLOVES

SGS Job No. : GZHL2001001495CW - GZ
Date of Sample Received : 11 Jan 2020
Testing Period : 11 Jan 2020 - 15 Jan 2020
Test Requested : Selected test(s) as requested by client.
Test Method : Please refer to next page(s).
Test Results : Please refer to next page(s).

Result Summary :

Table with 2 columns: Test Requested, Conclusion. Row 1: Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments- Overall migration, See Results

Signed for and on behalf of
SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch

Amy Ye

Amy Ye
Approved Signatory

scan to see the report



CANHG2000727801



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SGS-CSTC Standards Technical Services Co., Ltd
Guangzhou Branch Testing Center Chemical Laboratory

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中国·广州·经济技术开发区科学城科珠路198号 邮编: 510663 t (86-20) 82155555 f (86-20) 82075113 e sgs.china@sgs.com

Test Report

No. CANHG2000727801

Date: 15 Jan 2020

Page 2 of 3

Test Results :

Test Part Description :

Specimen No.	SGS Sample ID	Description	Material (claimed by the client)
SN1	CAN20-007278.001	White plastic glove	PVC

Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments– Overall migration

Test Method : With reference to Commission Regulation (EU) No 10/2011 of 14 January 2011 Annex III and Annex V for selection of condition and EN 1186-1:2002 for selection of test methods; or EN 1186-9:2002 aqueous food simulants by article filling method;

<u>Simulant Used</u>	<u>Time</u>	<u>Temperature</u>	<u>Max. Permissible Limit</u>	<u>Result of 001 Overall Migration</u>
3% Acetic Acid (W/V) Aqueous Solution	1.0hr(s)	40°C	10mg/dm ²	<3.0mg/dm ²
10% Ethanol (V/V) Aqueous Solution	1.0hr(s)	40°C	10mg/dm ²	<3.0mg/dm ²
20% Ethanol (V/V) Aqueous Solution	1.0hr(s)	40°C	10mg/dm ²	<3.0mg/dm ²
50% Ethanol (V/V) Aqueous Solution	1.0hr(s)	40°C	10mg/dm ²	<3.0mg/dm ²

Notes :

1. mg/dm² = milligram per square decimeter
mg/kg = milligram per kilogram of foodstuff in contact with
2. °C = degree Celsius
3. Analytical tolerance of aqueous simulants is 2mg/dm² or 12mg/kg
4. Analytical tolerance of fatty food simulants is 3mg/dm² or 20mg/kg

Remark: Test condition & simulant were specified by client.



SGS CSTC (Guangzhou) Technical Services Co., Ltd.
Guangzhou Branch Testing Center/Chemical Laboratory

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Sample photo:



SGS authenticate the photo on original report only

*** End of Report ***



SGS-CSTC 通标技术服务(广州)有限公司
Guangzhou Branch (Testing Center) Chemical Laboratory

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LEITAT
managing technologies

Notified Body nº 0162

EU type-examination Certificate

Regulation (EU) 2016/425

Personal Protective Equipment:

VINYL EXAMINATION GLOVES / Serial number 13-031

Applicant company :

CCIR ASIA PACIFIC LTD.

UNIT 20, 1/F, OFFICE BLOCK TWO, 96
SIENA AVENUE, DISCOVERY BAY
NORTH
HONG KONG
CHINA

EU Type Examination :

IN-00575-2019-OC-UE-E

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08225 Terrassa (Barcelona)



Consult our Certifications and Accreditations on our corporate website - www.leitat.org

EU-TYPE EXAMINATION (MODULE B) CERTIFICATE

Personal Protective Equipment (PPE)

LEITAT Technological Center, as Notified Body No. 0162

to issue the EU-Type Examination (Module B) Certificate,

CERTIFIES

That the prototype of Personal Protective Equipment:

VINYL EXAMINATION GLOVES / SERIAL NUMBER 13-031

Provided by the manufacturer:

CCIR ASIA PACIFIC LTD.

UNIT 20, 1/F, OFFICE BLOCK TWO, 96 SIENA AVENUE, DISCOVERY BAY NORTH
HONG KONG
CHINA

FULFILS with the essential health and safety requirements according to the exigencies established in the Regulation (EU) 2016/425, for

Protection against chemical risks and microorganism

according to EU-Type Examination (Module B) Report Number

IN-00575/2019-OC-UE-E

issued by this Notified Body and performed in accordance with the applicable parts of the Standards


EN 420:2003+A1:2009

EN ISO 374-1:2016 (Type C)

This certificate must be followed by conformity to type based on internal production control (Module C) plus supervised product control at random intervals (Module C2) or conformity to type based on quality assurance of the production process (Module D).


Sergi Artigas
Director of Innovation Strategy

Terrassa, April 12th 2019


Josep M. Pallarés
Certification Supervisor

This certificate is valid until April 12th 2024
This certificate is protected by the same conditions as the report it refers to

CERTIFICATION TECHNICAL REPORT

Report N°: IN-00575/2019-OC-E

Manufacturer	CCIR ASIA PACIFIC LTD.
Adress:	UNIT 20, 1/F, OFFICE BLOCK TWO, 96 SIENA AVENUE, DISCOVERY BAY NORTH
CP – Location:	HONG KONG
Province:	HONG KONG
Country:	CHINA

IDENTIFICATION OF PERSONAL PROTECTIVE EQUIPMENT

Sample presented	Glove
Reference	VINYL EXAMINATION GLOVES / Serial number 13-031
Quantity of sample submitted	150 units
Date of execution	28-02-19 to 8-04-19

APPLICABLE REGULATION

EN 420:2003+A1:2009 (Protective gloves. General requirements)
 EN ISO 374-1:2016 (Protective gloves against chemicals and micro-organisms. Terminology and performance requirements)

DOCUMENTATION PROVIDED

Technical report n° IN-00575-2019-B issued by LEITAT.

DESCRIPTION OF PERSONAL PROTECTIVE EQUIPMENT (PPE)

Glove made for protection against chemical risks and micro-organism

Five finger glove made by transparent vinyl.

SIZES

M

PHOTOGRAPH OF PERSONAL PROTECTIVE EQUIPMENT (PPE)

VINYL EXAMINATION GLOVES / Serial number 13-031



TESTS CARRIED OUT IN ACCORDANCE WITH APPLICABLE STANDARDS

ESSENTIAL HEALTH AND SAFETY REQUIREMENTS
(Regulation 2016/425. ANNEX II)

General requirements applicable to all PPE

<i>1. Design principles:</i>	
- Ergonomics	Visual inspection EN 420:2003+A1:2009, 4.1
- Levels and classes of protection	Defined by the manufacturer
<i>2. Harmlessness. Absence of inherent risks and other discomfort factors:</i>	EN 420:2003+A1:2009, 4.3.
- Suitable constituent materials	EN 420:2003+A1:2009, 4.3.
- The materials must not affect the health or safety of the user	EN 420:2003+A1:2009, 4.3.
- Satisfactory condition of all parts of the PPE that are in contact with the user	Visual inspection EN 420:2003+A1:2009, 4.1
<i>3. Comfort and efficiency:</i>	EN 420:2003+A1:2009, 5
- Adaptation to the user's morphology	EN 420:2003+A1:2009, 5.1.
- Lightness and solidity	Visual inspection EN 420:2003+A1:2009
- Compatibility with other PPE	Regulation 2016/425
- Manufacturer information instructions	EN 420:2003+A1:2009, 7.3. Regulation 2016/425

Additional requirements common to several types of PPE

- Adjustment system	Visual inspection EN 420:2003+A1:2009
- PPE that covers the parts of the body that must be protected. Sweating or absorption	EN 420:2003+A1:2009, 5.3.
- PPE exposed to ageing	EN 420:2003+A1:2009, 4.4.
- PPE with one or more indicators or identification markings, directly or indirectly related to health and safety	EN 420:2003+A1:2009, 7.2 Regulation 2016/425

Additional requirements specific to particular risks	
<i>1. Protection against skin contact:</i>	
- General requirements	EN ISO 374-1:2016 5.1
- Air leakage test	EN ISO 374-1:2016 5.2 EN 374-2:2014
- Water leakage test	EN ISO 374-1:2016 5.2 EN 374-2:2014
- Resistance to chemical degradation	EN ISO 374-1:2016 5.3 EN 374-4:2013
- Resistance to product permeation chemicals	EN ISO 374-1:2016 5.4 EN 16523-1:2015

RESULTADOS

“GUANTES DE PROTECCIÓN” “PROTECTIVE GLOVES”					
ENSAYO / TEST	APARTADO NORMATIVA / STANDARD CLAUSE	METODO DE ENSAYO / TEST METHOD	RESULTADOS / RESULTS		REQUERIMIENTO MÍNIMO / MINIMUM REQUIREMENT
CARACTERIZACIÓN DEL GUANTE / GLOVE CHARACTERIZATION					
	---	---	TALLA DEL GUANTE / SIZE OF THE GLOVE: M		---
TIPO DE MATERIAL / TYPE OF MATERIAL	---	---	Palma / Palm: Dorso / Back:	Material plástico / Plastic material	---
NÚMERO DE CAPAS / NUMBER OF LAYERS	---	---	Palma / Palm: Dorso / Back:	1 1	---
COLOR / COLOUR	---	---	Palma / Palm: Dorso / Back:	Transparente / Transparent	---
CARACTERIZACIÓN DEL MATERIAL / MATERIAL CHARACTERIZATION					
COMPOSICIÓN DEL MATERIAL / COMPOSITION OF MATERIAL	---		Palma / Palm: Dorso / Back:	Vinilo / Vinyl	---

EN 420:2003+A1:2009

“GUANTES DE PROTECCIÓN. REQUISITOS GENERALES Y MÉTODOS DE ENSAYO” “PROTECTIVE GLOVES. GENERAL REQUIREMENTS AND TEST METHODS”

ENSAYO / TEST	APARTADO NORMATIVA / STANDARD CLAUSE	METODO DE ENSAYO / TEST METHOD	RESULTADOS / RESULTS	REQUERIMIENTO MÍNIMO / MINIMUM REQUIREMENT	EVALUACIÓN / EVALUATION										
REQUISITOS GENERALES / GENERAL REQUIREMENTS															
OPCIONAL/ OPTIONAL.- RESISTENCIA A LA PENETRACIÓN DE AGUA / RESISTANCE TO WATER PENETRATION	3.16	<u>PIEL / LEATHER:</u> EN 344:1992 (5.12)	NA	<table border="1"> <tr> <td>Nivel prestación / Performance level</td> <td>Tiempo de penetración de agua / Time of water penetration (min):</td> </tr> <tr> <td>1</td> <td>> 30</td> </tr> <tr> <td>2</td> <td>> 60</td> </tr> <tr> <td>3</td> <td>> 120</td> </tr> <tr> <td>4</td> <td>> 180</td> </tr> </table>	Nivel prestación / Performance level	Tiempo de penetración de agua / Time of water penetration (min):	1	> 30	2	> 60	3	> 120	4	> 180	---
		Nivel prestación / Performance level	Tiempo de penetración de agua / Time of water penetration (min):												
		1	> 30												
		2	> 60												
		3	> 120												
4	> 180														
<u>TEXTIL:</u> EN 20811:1992	NA	---	---												
<u>PIEL / LEATHER:</u> ISO 4045:1977 EN ISO 4045:2008	NA	3,5 < x < 9,5	---												
<u>TEXTIL:</u> EN ISO 3071:2006	NA														
pH	4.3.2														
CUERO / LEATHER															
CONTENIDO EN CROMO VI / CONTENT ON CHROMIUM	4.3.3	ISO 17075	NA	< 3 mg/kg	---										
LATEX															
CONTENIDO EN PROTEINAS LIBRES / FREE CONTENT IN PROTEIN	4.3.4	EN 455-3:2006	NA	---	---										
OPCIONAL/ OPTIONAL.-															
PROPIEDADES ELECTROSTÁTICAS / ELECTROSTATIC PROPERTIES	4.3.5	EN 1149-1:2007 EN 1149-2:1998 EN 1149-3:2004	NA	---	---										

COMODIDAD Y EFICACIA / COMFORT AND EFFICIENCY						
TALLAS Y MEDIDAS DE LOS GUANTES / SIZES AND MEASURES OF THE GLOVES	5.1.2	EN 420:2004 (6.1)	TALLA DEL GUANTE / SIZE OF THE TALLA DEL GUANTE / SIZE OF THE GLOVE: M Longitud del guante / Length of the glove (mm) Mano derecha / Right hand: 245 Mano izquierda / Left hand: 240	Talla de la mano y del guante / Size of the hand and the glove	Longitud mínima del guante / Minimum length of the glove (mm)	CUMPLE COMPLIES
				6	220	
				7	230	
				8	240	
				9	250	
				10	260	
11	270					
DESTERIDAD / DEXTERITY	5.2.	EN 420:2004 (6.2)	5.0 mm	Nivel prestación / Performance level	Diámetro de la menor varilla / Diameter of smaller road (mm)	CUMPLE NIVEL 5 COMPLIES Level 5
				1	11,0	
				2	9,5	
				3	8,0	
				4	6,5	
5	5,0					
RESISTENCIA AL VAPOR DE AGUA / RESISTANCE TO WATER VAPOR (7-16 horas / hours)	5.3.1	EN 420:2004 (6.3) IUP 15	NA	> 5 mg/(cm ² h)		(*)
ABSORCIÓN DE VAPOR DE AGUA / ABSORPTION OF WATER VAPOR (8 horas/ hours)	5.3.1	EN 420:2004 (6.4)	<u>Palma / Palm</u> 0.06 ± 0.07 mg/cm²	> 8 mg/cm ²		(*)
(*) El período de utilización de este guante es limitado. Para períodos largos de uso, este se deberá usar junto a un guante interior que cumpla con los requisitos de confort de la norma EN420/03 +A1/09 / The period of use of this glove is limited. For long periods of use, it must be used in conjunction with an inner glove that meets the comfort requirements of EN420 / 03 + A1 / 09						

EN ISO 374-1:2016



“GUANTES DE PROTECCIÓN CONTRA LOS PRODUCTOS QUÍMICOS Y LOS MICROORGANISMOS” “PROTECTIVE GLOVES AGAINST CHEMICALS AND MICRO-ORGANISMS”

ENSAYO / TEST	APARTADO NORMATIVA / STANDARD CLAUSE	METODO DE ENSAYO / TEST METHOD	RESULTADOS / RESULTS	REQUERIMIENTO MÍNIMO / MINIMUM REQUIREMENT	EVALUACION EVALUATION
EN ISO 374-1:2016 TERMINOLOGIA Y REQUISITOS DE PRESTACIONES / TERMINOLOGY AND PERFORMANCE REQUIREMENTS					
REQUISITOS GENERALES / GENERAL REQUERIMENTS	5.1	EN 420:2003+A1 .2009 (4 y 5)	PASA / PASS	Ver EN 420:2004+A1.2009 (4 y 5)	CUMPLE COMPLIES
ENSAYO DE FUGA AL AIRE / TEST OF AIR LEAK	5.2	EN 374-2:2014 (7.2)	PENETRACIÓN / PENETRATION: NO HAY FUGA DE AIRE / NO AIR LEAKS	NO PASA / DON'T PASS	CUMPLE COMPLIES
ENSAYO DE FUGA AL AGUA / TEST OF WATER LEAK	5.2	EN 374-2:2014 (7.3)	PENETRACIÓN / PENETRATION: NO HAY FUGA DE AGUA / NO WATER LEAKS	NO PASA / DON'T PASS	CUMPLE COMPLIES
RESISTENCIA A LA DEGRADACIÓN POR LOS PRODUCTOS QUÍMICOS. ENSAYO DE PERFORACIÓN / DETERMINATION OF RESISTANCE TO DEGRADATION BY CHEMICALS. PERFORATION TEST. Ver tabla N° 1 / See table N° 1	5.3	EN 374-4:2013	PORCENTAJE DE CAMBIO EN LA RESISTENCIA A LA PENETRACION DEL MATERIAL / PERCENT CHANGE IN THE PUNCTURE OF THE MATERIAL: Material / material: PALMA / PALM Producto químico / Chemical product: NaOH 40% DR1 = 1.28 % DR2 = -20.97 % DR3 = -28.39 % DR = -16.0% DS = 15.4 % Cambio de aspecto del material / Change in the appearance of the material: Ninguno / None I (k=2) = ± 9.5%	-----	Valores informativos / Informative values

ENSAYO / TEST	APARTADO NORMATIVA / STANDARD CLAUSE	METODO DE ENSAYO / TEST METHOD	RESULTADOS / RESULTS				REQUERIMIENTO MÍNIMO / MINIMUM REQUIREMENT		EVALUACION EVALUATION		
			TIEMPO DE PASO / BREAKTHROUGH TIME (min)				Nivel prestación / Performance level	Tiempo de paso / Breakthrough time (min)			
			Código Letter code	Tiempo / Time (min)	Forro/ lining	Observaciones/ Observations					
RESISTENCIA A LA PERMEACIÓN POR PRODUCTOS QUÍMICOS / RESISTANCE TO PERMEATION BY CHEMICALS Ver tabla N° 1 / See table N° 1	5.4	EN 16523-1:2015	PALMA/ PALM				1	> 10	K: NaOH 40%: CUMPLE/COMPLIES NIVEL 6 / LEVEL 6		
			K	> 480 min	NA	Ligero cambio de color Slight change of color					
										2	> 30
										3	> 60
										4	> 120
										5	> 240
										6	> 480

PICTOGRAMA / PICTOGRAM

EN ISO 374-1 Tipo/Type C

PRODUCTOS QUÍMICOS / CHEMICAL PRODUCTS

K: Hidróxido sódico 40 % / Sodium hydroxide 40 % (NaOH 40%)

K

Clasificación de los guantes / Gloves classification

Guantes Tipo A: El ensayo de permeación debe ser de al menos nivel 2 en un mínimo de 6 productos químicos /
 Glove type A: Permeation test shall be at least level 2 against minimum 6 chemical products.

Guantes Tipo B: El ensayo de permeación debe ser de al menos nivel 2 en un mínimo de 3 productos químicos /
 Glove type B: Permeation test shall be at least level 2 against minimum 3 chemical products.

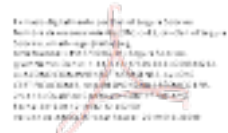
Guantes Tipo C: El ensayo de permeación debe ser de al menos nivel 1 en un mínimo de 1 productos químicos /
 Glove type C: Permeation test shall be at least level 1 against minimum 1 chemical products.

TABLA / TABLE 1			
Código Letter code	Producto químico/ Chemical	NÚMERO CAS CAS NUMBER	CLASE / CLASS
A	Metanol/ <i>Methanol</i>	67-56-1	Alcohol primario/ <i>Primary alcohol</i>
B	Acetona / <i>Acetone</i>	67-64-1	Cetona / <i>Ketone</i>
C	Acetonitrilo/ <i>Acetonitrile</i>	75-05-8	Compuesto nitrilo / <i>Nitrile compound</i>
D	Diclorometano/ <i>Dichloromethane</i>	75-09-2	Hidrocarburo clorado/ <i>Chlorinated hydrocarbon</i>
E	Disulfuro de carbono / <i>Carbon Disulphire</i>	75-15-0	Compuesto orgánico que contiene azufre / <i>Sulphur containing organic compound</i>
F	Tolueno/ <i>Toluene</i> :	108-88-3	Hidrocarburo aromático / <i>Aromatic hydrocarbon</i>
G	Dietilamina / <i>Diethilamine</i> :	109-89-7	Amina / <i>Amine</i>
H	Tetrahidrofurano/ <i>Tetrahydrofuran</i>	109-99-9	Compuestos heterocíclicos y éter / <i>Heterocyclic and ether compound</i>
I	Acetato de etilo / <i>Ethyl acetate</i>	141-78-6	Ester / <i>Ester</i>
J	n- Heptano / <i>n- Heptane</i>	142-82-5	Hidrocarburo saturado/ <i>Saturated hydrocarbon</i>
K	Hidróxido sódico 40 % / <i>Sodium hidroxide 40% (NaOH 40%)</i>	1310-73-2	Base inorgánica / <i>Inorganic base</i>
L	Acido sulfúrico 96 % / <i>Sulphuric acid 96 % (H₂SO₄ 96%)</i>	7664-93-9	Ácido mineral inorgánico, / oxidante/ <i>Inorganic mineral acid, oxidizing</i>
M	Acido Nítrico 65 % / <i>Nitric Acid 65 %</i>	7697-37-2	Ácido mineral inorgánico, oxidante / <i>Inorganic mineral acid, oxidizing</i>
N	Acido acético 99 % / <i>Acetic Acid 99 %</i>	64-19-7	Ácido orgánico / <i>Organic acid</i>
O	Hidróxido Amónico 25 % / <i>Amminium hydroxide 25 %</i>	1336-21-6	Base orgánica / <i>Organic base</i>
P	Peróxido de Hidrógeno 30 % / <i>Hydrogen Peroxide 33 %</i>	7722-84-1	Peróxido / <i>Peroxide</i>
S	Acido Hidrofluórico 40 % / <i>Hydrofluoric acid 40 %</i>	7664-39-3	Ácido mineral inorgánico/ <i>Inorganic mineral acid</i>
T	Formaldehido 37 % / <i>Formaldehyde 37 %</i>	50-00-0	Aldehído / <i>Aldehyde</i>

NA can be interpreted as:

- Do not apply, because the material is not the specified on the test standard
- In case of actualization or extension, not considered as critical test
- Do not proceed because of the design of the PPE and the expected use
- Not compulsory or optional requirement not requested by the PPEs manufacturer.

Validated by :

Technical Responsible of PPE Certifications
 Daniel Segura Sobrino

Terrassa, April 12th 2019.

CCIR ASIA PACIFIC LIMITED

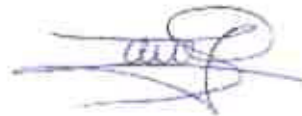
Suite 1803, 18 Floor, Beautiful Group Tower
77 Connaught Road Central
Hong Kong

Terrassa, 10 de Febrero de 2014

Dear Sirs:

The purpose of this letter is to inform you that the reference glove " **VINYL GLOVE FOR ONE USE** " included in the certificate No. IN-01657-2013-OC-CE-E-1 and its actualization IN-01657-2013-OC-CE-E-2 to name of **CCIR ASIA PACIFIC LIMITED** should be considered as **CAT III PPE**.

Best regards,



Organismo de Control N° 0162

Technical Responsible of PPE certification

Daniel Segura

CERTIFICADO DE ENSAYO / TEST CERTIFICATE

LEITAT – Technological Centre

CERTIFICA / CERTIFIES

Que el artículo referenciado como / *That article reference as:*

GUANTES DE EXPLORACIÓN/PROCEDIMIENTO DE VINILO
EXAMINATION / PROCEDURE VINYL GLOVES

Presentado por el fabricante / *Presented by the manufacturer:*

CCIR ASIA PACIFIC LIMITED
Suite 1803, 18 Floor, Beautiful Group Tower
77 Connaught Road Central
Hong Kong

CUMPLE con los requisitos para / *FULFILLS with the requirements for:*

“Guantes de exploración/procedimiento hechos de otros materiales termoplásticos” /
“Examination-Procedure gloves made of other thermoplastic materials”
(Tabla / Table 3 – UNE-EN 455-2:2010+A1:2011)

de acuerdo al informe técnico número / *according to the technical report number:*

IN-03241/2014-B-4

de este laboratorio y realizado en base a los puntos aplicables de las normas **UNE-EN 455-1:2001, UNE-EN 455-2:2010+A1:2011 y UNE-EN 455-3:2007** para **“Guantes médicos de un solo uso”** / of this laboratory and performed according the applicable items of the standards **UNE-EN 455-1:2001, UNE-EN 455-2:2010+A1:2011 y UNE-EN 455-3:2007** for **“Medical gloves for single use”**


Miquel Moreda
Responsable Técnico /
Technical Manager

Terrassa, 16 de Enero de 2015 /
Terrassa, January 16th, 2015

Este certificado de ensayo no da fe mas que de la muestra presentada por el cliente y ensayada según los métodos y condiciones detalladas en el informe de ensayo. No se refiere en ningún caso a la aprobación, certificación, supervisión, control o vigilancia realizada por el LEITAT Centro Tecnológico sobre este o cualquier otro producto relacionado. / *This test certificate testifies only about the sample presented for the customer and tested according to the methods and conditions detailed its testing report. The certificate does not refer in any case to the approval, certification, supervision, control or vigilance done by LEITAT Technological Centre for this or any other product connected.*

CCIR ASIA PACIFIC LIMITED
Suite 1803, 18 Floor, Beautiful Group Tower
77 Connaught Road Central
Hong Kong

ACTUALIZATION of EC TYPE-EXAMINATION
Nº IN-01657-2013-OC-CE-E-1/22/07/13

Núm. Informe: IN-01657/2013-OC-CE-E-2
Total Páginas: 2

The Acondicionamiento Tarrasense Laboratory of Textile Research and Trials (LEITAT), as no. 0162 Notified Body for Spain to issue the EC type-examination certificate,

CERTIFIES:

That the prototype for the protection gloves with the following reference:

VINYL GLOVE FOR ONE USE

that holds the EC Type Examination Certificate issued by this Laboratory with report no. IN-01657-2013-OC-CE-E-1 dated 22nd July 2013, **COMPLIES** with EN 420/03+A1/09 and EN 374-3/03+AC/06, being that the new amendment of the standard does not involve changes in the original EC.

This actualization of certification is valid for the articles referenced above.

This actualization of certification does not question compliance with the essential requirements verified when the appropriate EC TYPE EXAMINATION CERTIFICATE was issued.

Any change made to the PPE under this actualization of certification must be reported to the Notified Body.

SUPERVISOR CERTIFICACIÓN

Josep M^a Pallarés Soler

Terrassa, 22th July, 2013

“Only is authorized the use of our NB identification number in those documents in which the Directive therefore requires it (Informative Pamphlet and Technical Documentation)”

EC-TYPE EXAMINATION CERTIFICATE

Personal Protective Equipment (PPE)

LEITAT Technological Center, as Notified Inspection Body No. 0162

to issue the EC-Type Examination Certificate,

CERTIFIES

That the prototype of Personal Protective Equipment:

VINYL GLOVE FOR ONE USE

Provided by the manufacturer:

CCIR ASIA PACIFIC LIMITED

Suite 1803, 18 Floor, Beautiful Group Tower
77 Connaught Road Central - Hong Kong

FULFILLS the exigencies established in the Directive 89/686/EEC, for

Protective Gloves against chemicals and microorganisms

according to EC-Type Examination Report Number

IN-01657-2013-OC-CE-E-1 and its actualization IN-01657-2013-OC-CE-E-2

issued by this Laboratory and performed in accordance with the applicable parts of the Standards

EN 420/03+A1/09

EN 374-1/03

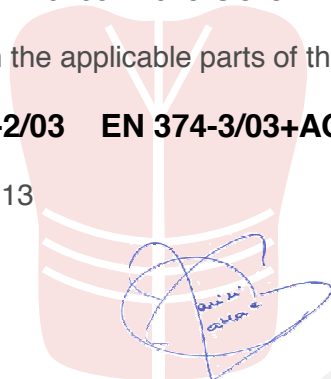
EN 374-2/03

EN 374-3/03+AC/06

Terrassa, July 22nd, 2013



Sergi Artigas
Corporation Development Manager



Josep Mª Pallarès
Certification Supervisor

Informe interpretable de Firma Electrónica



ANF AC
AUTORIDAD DE CERTIFICACIÓN
TRADISE

Resumen de Firma

Firma 1

Páginas firmadas: De la 1 a la 3
Firmante(s):
Nombre: JOSE MARIA PALLARES SOLER
Fecha:¹ 2013/07/22 13:58:37
Documento jurídico adjunto: firma_juridica.slc
Nombre documento original: IN-01657-2013-OC-CE-E-2.pdf

IMPORTANTE

Esta visualización es una representación gráfica interpretable de la Firma Electrónica integrada en este documento. Para confiar en los datos mostrados, es imprescindible obtenerlos desde el documento de firma adjunto a este documento PDF, único documento que garantiza la seguridad y validez jurídica de la firma. Para realizar estas acciones puede descargar el dispositivo de verificación homologado por ANF AC en

<https://www.anf.es/exe/eSLCViewer.exe>

Esta firma electrónica cumple los requerimientos establecidos por la Ley de Firma Electrónica 59/2003 en el art. 24.3 en materia de firma electrónica reconocida.

¹ UTC (Tiempo Universal Coordinado, no se aplica desplazamiento horario verano-invierno)



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Páginas sección firma: 1