

CERTIFICATE OF CE (MDD) NOTIFICATION

Ref. No.: JP 3621-2014

Date: 19/01/2015

Order No.: JP 3593-2014

THIS IS TO CERTIFY THAT, ACCORDING TO THE EUROPEAN COUNCIL DIRECTIVE 93/42/EEC WE, HERE AT OBELIS S.A. (O.E.A.R.C.) PERFORMED ALL NOTIFICATION DUTIES AND RESPONSIBILITIES AS THE EUROPEAN AUTHORIZED REPRESENTATIVE (EC REP) OF:

NAME: TAN SIN LIAN INDUSTRIES SDN. BHD.

ADDRESS: NO. 1-14, JALAN INDAH 2, TAMAN INDAH, JALAN HAJI ABDULLAH, 84000 MUAR, JOHOR, MALAYSIA

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED DIRECTIVE.

The Manufacturer declares that the Class I * devices comply with the Directive including all essential requirements.

The Manufacturer has provided Obelis s.a. (O.E.A.R.C.) with all the appropriate declarations as per the European Council Directive 93/42/EEC article 14 requirements, including the EC Declaration of Conformity (according to Annex VII) confirming that their Class I medical devices, as stipulated here below, are fulfilling the applicable requirements of the European Council Directive 93/42/EEC.

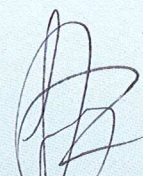
The notification of the following medical devices has been completed by Obelis s.a. (O.E.A.R.C.) on the 12th of September 2000 in compliance with the European Council Directive 93/42/EEC - article 14 requirements.

CLASS I MEDICAL DEVICE(S): PLEASE SEE ANNEX A - LIST OF DEVICES (1 PAGE 2 DEVICES)

As of the 13th of September 2000, and as long as the Manufacturer will continue complying with the hereabove mentioned requirements**, he therefore:

- Is required to affix the CE marking on these devices;
- May place these devices in the European community territory,

SEEN
by the Brussels Chamber of Commerce
Evelien Jonckheere
Brussels, the 22 JAN. 2015

P.O.  S. FERRETTI
C.C.O.

Mr. G. Elkayam CEO
Obelis sa

date & stamp

Brussels Enterprise
Commerce & Industry

date & stamp

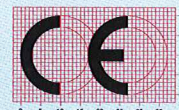
Obelis s.a.
Registered Address :
Bld Général Wahis 53
1030 Bruxelles

+32 2 732 5954 Fax: +32 2 732 6003
Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001:2008 and ISO 13485:2003 certified in accordance to the profession of a European Authorized Representative.



*also applicable to Class I s & m

** and provided that the product classification will not be rejected by the competent authorities



Annex A* – List of devices

(Article 9, section 1 of the Directive 93/42/EEC on medical devices)

No.	Generic Device Term	Commercial name	Class**	Rule	Catalogue reference number	Short description and intended use
1	Latex Examination Gloves Powdered and Powder Free	Powdered Latex Examination Gloves	I	1	N/A	Non Sterile, Ambidextrous, Made by Natural Rubber Use by healthcare personnel. Worn over hands as a biological barrier
		Powder Free Latex Examination Gloves	I	1	N/A	Non Sterile, Ambidextrous, Made by Natural Rubber Use by healthcare personnel. Worn over hands as a biological barrier
2	Nitrile Examination Gloves Powder Free	Nitrile Examination Gloves	I	1	N/A	Non Sterile, Ambidextrous, Made by Natural Rubber Use by healthcare personnel. Worn over hands as a biological barrier

* Annex A is part of the Agreement.

** The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (MDD 93/42/EEC, article 2 & Annex IX; MEDDEV 2.4/1 Rev.9, chapter 3.1 & 3.3)

*** GMDN codes are mandatory information to perform the Notification

Manufacturer's Name

Tan Sin Lian Industries Sdn. Bhd.

Signature: _____

Date: 09/12/2014

Stamp:



Obelis S.A.

Signature: _____

Date: 22/01/2015

Stamp:

S. FERRETTI
C.C.O.



Stamp:

Obelis s.a.
 Registered Address:
 Bld Général Wabis F3
 1030 Bruxelles

Page 1 of 1

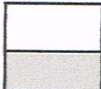
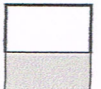
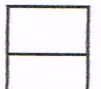
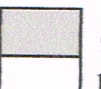
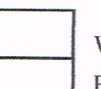

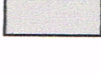
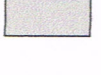
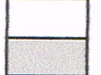
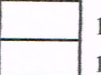
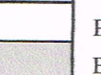
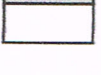
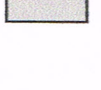
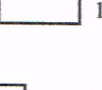
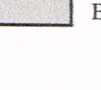
Tél. +32 2 732 59 54 - Fax +32 2 732 60 07

Date of Inspection	Customer	Brand Name/Reference
30/04/2020	SUINCE SL (Spain)	Capital Gloves/SSL-01

General Product Description and Size Breakdown:

Non-Sterile Nitrile Examination Gloves, Powder Free, Fingertips Textured, 230mm

Size	XS	S	M	L	XL	Total
Quantity (Pcs)	-	50,000	400,000	450,000	100,000	1,000,000

 NR	 PP	 Smooth	 9"	 White	 Beaded
 NT	 PF	 PT	 11"	 Blue	 Beadless
		 FT	 12"	 Black	

Type Of Inspection:

 ASTM	 EN	 (Others)
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Inspection/ Test	AQL	Inspection Level	No. of Samples	Size Breakdown					Accept/ Reject	Found	Pass/ Fail
				XS	S	M	L	XL			
Watertight Test	1.5	G1	500	-	25	200	225	50	14/15	10	Passed
Visual Inspect (Major)	2.5	G1	500	-	25	200	225	50	21/22	9	Passed
Visual Inspect (Minor)	4.0	G1	315	-	16	126	142	31	21/22	13	Passed
Physical Dimension	4.0	S2	13	-	1	5	6	1	1/2	0	Passed

Notes/Remark:

NIL

INSPECTION AND TEST DETAILS (I):

Watertight Test Inspection	Size					Visual Inspect (Major)	Size					Visual Inspect (Minor)	Size				
	XS	S	M	L	XL		XS	S	M	L	XL		XS	S	M	L	XL
PHFT			1	2		Touching						Sticky<10mm					
PHF	1	1	2	1		Pinhole			1	2	1	Dirt<1mm			1		
PHCrotch				1		Tear			1	1		Lump<100			2	1	
PHP			1			Sticky>10mm						Thin Spot		1		1	1
PHC						Large Lump			1	1		Fish Eye		1	1	2	2
TC						Dirt>1mm				1		WBF					
TR						Poor Beading											
LD						E. Powder											
						Rolled Cuff											
						Inv. Finger											
Found	10					Found	9					Found	13				

Notes and Remark:

PHFT : Pinhole Finger Tip	TR : Tear
PHF : Pinhole along Finger	WBF : Weak Between Finger
PHCrotch : Pinhole at Crotch	E. Powder: Excess Powder
PHP : Pinhole at Palm	Inv. Finger : Inverted Finger
PHC : Pinhole at Cuff	
TC : Touching	

INSPECTION AND TEST DETAILS (II):

Type of Packaging		Counting	Size				
Type	Quantity/Packaging		XS	S	M	L	XL
Type 1	100pcs/Box	Quantity	-	100	100	100	100
Type 2	100pcs/Box	Quantity	-	100	100	100	100
Type 3	100pcs/Box	Quantity	-	101	100	100	100

Notes and Remark:
NIL

INSPECTION AND TEST DETAILS (III):**Type Of Inspection:**

ASTM EN _____ (Others)

Physical Dimension Inspection (mm)

No.	Size	Weight	Product Code	Length	Width	Cuff	Palm	Finger Tips
1	S	3.20	35	243	85	0.05	0.06	0.11
2	M	3.60	35	243	95	0.06	0.07	0.12
3	M	3.50	35	240	95	0.05	0.06	0.10
4	M	3.70	35	245	96	0.06	0.07	0.11
5	M	3.50	35	243	95	0.06	0.07	0.12
6	M	3.60	35	242	95	0.05	0.06	0.11
7	L	4.00	35	240	105	0.05	0.06	0.11
8	L	3.90	35	245	104	0.05	0.06	0.10
9	L	4.00	35	242	105	0.06	0.07	0.12
10	L	3.90	35	240	104	0.05	0.06	0.10
11	L	4.20	35	240	105	0.05	0.06	0.10
12	L	4.10	35	242	105	0.06	0.07	0.11
13	XL	4.50	35	240	115	0.05	0.06	0.10

Min. Length Requirements: 230mm

Min. Thickness Requirements: 0.05mm (Palm and Finger Tips)

OTHER INSPECTION AND TEST DETAILS (IV):

If any, provide inspection/test as attachment.

S – 91125630

M – 91125630

L – 91125630, 90914630

XL – 91125633

QA Inspectors:

Sarimah
Amin
Fizah

Date: 30/04/2020

QA:

Sarimah
Amin
Fizah

Date: 30/04/2020

Managing Director/QA Manager:



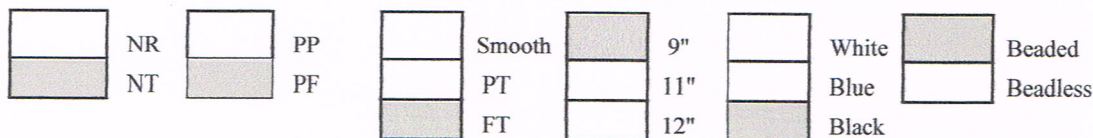
Date: 30/04/2020

Date of Inspection	Customer	Brand Name/Reference
30/04/2020	SUINCE SL (Spain)	Doctor/SSL-01

General Product Description and Size Breakdown:

Non-Sterile Nitrile Examination Gloves, Powder Free, Fingertips Textured, 230mm

Size	XS	S	M	L	XL	Total
Quantity (Pcs)	-	-	212,000	213,000	75,000	500,000



Type Of Inspection:



Inspection/ Test	AQL	Inspection Level	No. of Samples	Size Breakdown					Accept/ Reject	Found	Pass/ Fail
				XS	S	M	L	XL			
Watertight Test	1.5	G1	500	-	-	213	213	74	14/15	12	Passed
Visual Inspect (Major)	2.5	G1	500	-	-	213	213	74	21/22	11	Passed
Visual Inspect (Minor)	4.0	G1	315	-	-	134	134	47	21/22	13	Passed
Physical Dimension	4.0	S2	13	-	-	5	6	2	1/2	0	Passed

Notes/Remark:

NIL

INSPECTION AND TEST DETAILS (I):

Watertight Test Inspection	Size					Visual Inspect (Major)	Size					Visual Inspect (Minor)	Size				
	XS	S	M	L	XL		XS	S	M	L	XL		XS	S	M	L	XL
PHFT			1	2	2	Touching						Sticky<10mm					
PHF			1	1	2	Pinhole			1	2	1	Dirt<1mm					1
PHCrotch				1		Tear				1		Lump<100			3	2	
PHP					1	Sticky>10mm						Thin Spot				1	1
PHC				1		Large Lump			1			Fish Eye			1	3	1
TC						Dirt>1mm				1	1	WBF					
TR						Poor Beading			2	1							
LD						E. Powder											
						Rolled Cuff											
						Inv. Finger											
Found	12					Found	11					Found	13				

Notes and Remark:

- PHFT : Pinhole Finger Tip
- PHF : Pinhole along Finger
- PHCrotch : Pinhole at Crotch
- PHP : Pinhole at Palm
- PHC : Pinhole at Cuff
- TC : Touching
- TR : Tear
- WBF : Weak Between Finger
- E. Powder: Excess Powder
- Inv. Finger : Inverted Finger

INSPECTION AND TEST DETAILS (II):

Type of Packaging		Counting	Size				
Type	Quantity/Packaging		XS	S	M	L	XL
Type 1	100pcs/Box	Quantity	-	-	100	100	100
Type 2	100pcs/Box	Quantity	-	-	101	100	100
Type 3	100pcs/Box	Quantity	-	-	100	100	100

Notes and Remark:
NIL

INSPECTION AND TEST DETAILS (III):**Type Of Inspection:**

ASTM EN _____ (Others)

Physical Dimension Inspection (mm)

No.	Size	Weight	Product Code	Length	Width	Cuff	Palm	Finger Tips
1	M	3.50	35	240	95	0.06	0.07	0.10
2	M	3.40	35	243	95	0.05	0.06	0.09
3	M	3.50	35	240	96	0.06	0.07	0.10
4	M	3.60	35	242	95	0.05	0.06	0.10
5	M	3.50	35	240	95	0.05	0.06	0.10
6	L	3.90	35	240	105	0.06	0.07	0.11
7	L	4.00	35	240	106	0.05	0.06	0.09
8	L	4.00	35	240	105	0.05	0.06	0.10
9	L	3.90	35	242	105	0.05	0.06	0.10
10	L	3.90	35	241	106	0.06	0.07	0.11
11	L	4.00	35	241	105	0.06	0.07	0.10
12	XL	4.50	35	240	116	0.05	0.06	0.09
13	XL	4.40	35	240	115	0.05	0.06	0.09

Min. Length Requirements: 230mm

Min. Thickness Requirements: 0.05mm (Palm and Finger Tips)

OTHER INSPECTION AND TEST DETAILS (IV):

If any, provide inspection/test as attachment.

M – 00220775

L – 00220775

XL – 00220775

QA Inspectors:

Sarimah
Amin
Fizah
Nurul

Date: 30/04/2020

QA:

Sarimah
Amin
Fizah
Nurul

Date: 30/04/2020

Managing Director/QA Manager:



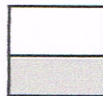
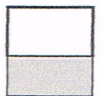
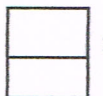
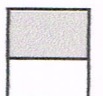
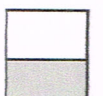

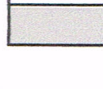
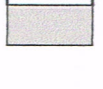
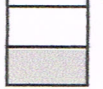
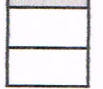
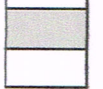
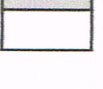
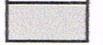
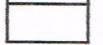
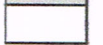
Date: 30/04/2020

Date of Inspection	Customer	Brand Name/Reference
30/04/2020	SUINCE SL (Spain)	Doctor/SSL-01

General Product Description and Size Breakdown:

Non-Sterile Nitrile Examination Gloves, Powder Free, Fingertips Textured, 230mm

Size	XS	S	M	L	XL	Total
Quantity (Pcs)	-	-	-	440,000	265,000	705,000

 NR	 PP	 Smooth	 9"	 White	 Beaded
 NT	 PF	 PT	 11"	 Blue	 Beadless
		 FT	 12"	 Black	

Type Of Inspection:

 ASTM	 EN	 (Others)
----------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------

Inspection/ Test	AQL	Inspection Level	No. of Samples	Size Breakdown					Accept/ Reject	Found	Pass/ Fail
				XS	S	M	L	XL			
Watertight Test	2.5	G1	500	-	-	-	312	188	21/22	13	Passed
Visual Inspect (Major)	2.5	G1	500	-	-	-	312	188	21/22	12	Passed
Visual Inspect (Minor)	4.0	G1	315	-	-	-	197	118	21/22	14	Passed
Physical Dimension	4.0	S2	13	-	-	-	8	5	1/2	0	Passed

Notes/Remark:

NIL

INSPECTION AND TEST DETAILS (I):

Watertight Test Inspection	Size					Visual Inspect (Major)	Size					Visual Inspect (Minor)	Size				
	XS	S	M	L	XL		XS	S	M	L	XL		XS	S	M	L	XL
PHFT				2	3	Touching						Sticky<10mm					
PHF				2	2	Pinhole				2	3	Dirt<1mm				2	2
PHCrotch					1	Tear				1		Lump<100				1	
PHP				1		Sticky>10mm						Thin Spot				3	2
PHC				1	1	Large Lump						Fish Eye				3	1
TC						Dirt>1mm				2	1	WBF					
TR						Poor Beading				2	1						
LD						E. Powder											
						Rolled Cuff											
						Inv. Finger											
Found	13					Found	12					Found	14				

Notes and Remark:

PHFT : Pinhole Finger Tip	TR : Tear
PHF : Pinhole along Finger	WBF : Weak Between Finger
PHCrotch : Pinhole at Crotch	E. Powder: Excess Powder
PHP : Pinhole at Palm	Inv. Finger : Inverted Finger
PHC : Pinhole at Cuff	
TC : Touching	

INSPECTION AND TEST DETAILS (II):

Type of Packaging		Counting	Size				
Type	Quantity/Packaging		XS	S	M	L	XL
Type 1	100pcs/Box	Quantity	-	-	-	100	100
Type 2	100pcs/Box	Quantity	-	-	-	100	100
Type 3	100pcs/Box	Quantity	-	-	-	100	100

Notes and Remark:
NIL

INSPECTION AND TEST DETAILS (III):**Type Of Inspection:**

ASTM EN _____ (Others)

Physical Dimension Inspection (mm)

No.	Size	Weight	Product Code	Length	Width	Cuff	Palm	Finger Tips
1	L	3.50	30	245	105	0.05	0.06	0.08
2	L	3.50	30	242	104	0.05	0.06	0.08
3	L	3.40	30	242	106	0.06	0.07	0.09
4	L	3.50	30	240	106	0.06	0.07	0.10
5	L	3.50	30	240	105	0.05	0.06	0.08
6	L	3.60	30	243	105	0.05	0.06	0.09
7	L	3.50	30	242	104	0.06	0.07	0.09
8	L	3.50	30	245	105	0.05	0.06	0.08
9	XL	4.00	30	241	115	0.05	0.06	0.09
10	XL	3.90	30	242	116	0.06	0.07	0.09
11	XL	3.90	30	242	115	0.05	0.06	0.08
12	XL	4.00	30	240	114	0.06	0.07	0.09
13	XL	4.00	30	240	115	0.05	0.06	0.08

Min. Length Requirements: 230mm

Min. Thickness Requirements: 0.05mm (Palm and Finger Tips)

OTHER INSPECTION AND TEST DETAILS (IV):

If any, provide inspection/test as attachment.

L – 91231600, 00115690, 00130600

XL – 00115693, 00115690

QA Inspectors:

Sarimah
Amin
Fizah
Nurul

Date: 30/04/2020

QA:

Sarimah
Amin
Fizah
Nurul

Date: 30/04/2020

Managing Director/QA Manager:



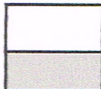
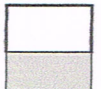

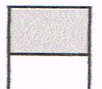
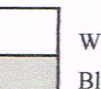

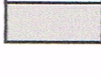
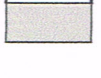
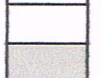
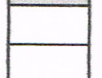
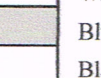
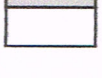
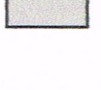
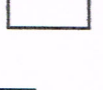
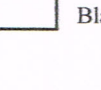
Date: 30/04/2020

Date of Inspection	Customer	Brand Name/Reference
30/04/2020	SUINCE SL (Spain)	Doctor/SSL-01

General Product Description and Size Breakdown:

Non-Sterile Nitrile Examination Gloves, Powder Free, Fingertips Textured, 230mm

Size	XS	S	M	L	XL	Total
Quantity (Pcs)	-	-	755,000	755,000	265,000	1,775,000

 NR	 PP	 Smooth	 9"	 White	 Beaded
 NT	 PF	 PT	 11"	 Blue	 Beadless
		 FT	 12"	 Black	

Type Of Inspection:

 ASTM	 EN	 (Others)
----------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------

Inspection/ Test	AQL	Inspection Level	No. of Samples	Size Breakdown					Accept/ Reject	Found	Pass/ Fail
				XS	S	M	L	XL			
Watertight Test	2.5	G1	500	-	-	213	213	74	21/22	13	Passed
Visual Inspect (Major)	2.5	G1	500	-	-	213	213	74	21/22	12	Passed
Visual Inspect (Minor)	4.0	G1	315	-	-	134	134	47	21/22	14	Passed
Physical Dimension	4.0	S2	13	-	-	5	6	2	1/2	0	Passed

Notes/Remark:

NIL

INSPECTION AND TEST DETAILS (I):

Watertight Test Inspection	Size					Visual Inspect (Major)	Size					Visual Inspect (Minor)	Size				
	XS	S	M	L	XL		XS	S	M	L	XL		XS	S	M	L	XL
PHFT			1	1	2	Touching						Sticky<10mm					
PHF				1	2	Pinhole			1	2	3	Dirt<1mm			2	1	1
PHCrotch					1	Tear					1	Lump<100				1	
PHP				2		Sticky>10mm						Thin Spot			1	2	1
PHC				1	2	Large Lump						Fish Eye			3	1	1
TC						Dirt>1mm			2		1	WBF					
TR						Poor Beading				1	1						
LD						E. Powder											
						Rolled Cuff											
						Inv. Finger											
Found	13					Found	12					Found	14				

Notes and Remark:

PHFT : Pinhole Finger Tip
 PHF : Pinhole along Finger
 PHCrotch : Pinhole at Crotch
 PHP : Pinhole at Palm
 PHC : Pinhole at Cuff
 TC : Touching

TR : Tear
 WBF : Weak Between Finger
 E. Powder: Excess Powder
 Inv. Finger : Inverted Finger

INSPECTION AND TEST DETAILS (II):

Type of Packaging		Counting	Size				
Type	Quantity/Packaging		XS	S	M	L	XL
Type 1	100pcs/Box	Quantity	-	-	101	100	100
Type 2	100pcs/Box	Quantity	-	-	100	100	100
Type 3	100pcs/Box	Quantity	-	-	100	100	100

Notes and Remark:

NIL

INSPECTION AND TEST DETAILS (III):**Type Of Inspection:**
 ASTM EN _____ (Others)
Physical Dimension Inspection (mm)

No.	Size	Weight	Product Code	Length	Width	Cuff	Palm	Finger Tips
1	M	2.50	25	240	95	0.05	0.06	0.08
2	M	2.50	25	241	94	0.04	0.05	0.07
3	M	2.40	25	241	96	0.05	0.06	0.08
4	M	2.60	25	242	94	0.05	0.06	0.08
5	M	2.50	25	240	95	0.04	0.05	0.07
6	L	3.00	25	240	104	0.04	0.05	0.07
7	L	3.10	25	242	105	0.05	0.06	0.08
8	L	3.00	25	240	105	0.05	0.06	0.08
9	L	2.90	25	240	104	0.05	0.06	0.07
10	L	3.00	25	243	106	0.05	0.06	0.08
11	L	3.00	25	242	105	0.04	0.05	0.07
12	XL	3.50	25	241	115	0.04	0.05	0.07
13	XL	3.40	25	240	115	0.05	0.06	0.08

Min. Length Requirements: 230mm

Min. Thickness Requirements: 0.05mm (Palm and Finger Tips)

OTHER INSPECTION AND TEST DETAILS (IV):

If any, provide inspection/test as attachment.

M – 00227772

L – 00214772, 00212772

XL – 00227772

QA Inspectors:

Sarimah
Amin
Fizah
Nurul

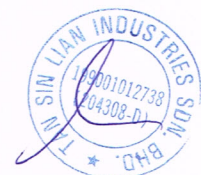
Date: 30/04/2020

QA:

Sarimah
Amin
Fizah
Nurul

Date: 30/04/2020

Managing Director/QA Manager:



Date: 30/04/2020