Powder-Free Nitrile Examination Gloves

Supplier Code: MY-ND

Product Specification

DESIGN & FEATURE				
Type	Powder-Free and non-sterile examination gloves			
Material	Nitrile Butadiene Rubber Latex			
Design	Beaded cuff ,Powder-free,Ambidextrous.			
Colour	Coral Blue			
PHYSICAL DIMENSION				
Dimension - Palm Width (mm)		(ASTM 6319)		(EN 455-2)
	Size S	: 80 ± 10	Size S	: 80 ± 10
	Size M	: 95 ± 10	Size M	: 95 ± 10
	Size L	: 110 ± 10	Size L	: 110 ± 10
Dimension - Glove Length (mm)	Size S	: 220 min	Size S	: ≥ 240
	Size M	: 230 min	Size M	: ≥ 240
	Size L	: 230 min	Size L	: ≥ 240
Thickness (Single Wall) (mm)	Finger	: 0.050 min		
	Palm	: 0.050 min		
PHYSICAL PROPERTIES				
ASTM D6319				
Tensile Strength (MPa)	Unaged	: 14 min	Aged	: 14 min
Ultimate Elongation (%)	Unaged	: 500 min	Aged	: 400 min
EN 455-2				
Force at Break (N)	Unaged	: Mediar ≥ 6N	Aged	: Median ≥ 6N
POWDER CONTENT				
Powder Content (ASTM D6124)	Max 2 mg/g			
PRODUCT INFORMATION				
Manufactured Date	YYYY-MM (YYYY = Year, MM = Month)			
Expiry Date	YYYY-MM (YYYY = Year, MM = Month)			
Shelf-Life	5 years from the date of manufacture			
Packing configuration	100 pcs by weight/dispenser box, 10 dispenser boxes/carton			
	200 pcs by weight/dispenser box, 10 dispenser boxes/carton			
Storage Condition	Cool dry place, Avoid direct sunlight			

PRESHIPMENT INSPECTION- CRITICAL, FUNCTIONAL & VISUAL DEFECTS (Sampling Plan ISO 2859)		
	Inspection Level	**AQL**
1000 mL water leak test	G1	1.5
Visual Inspection		
a) Critical Defects	Not Acceptable	Not Acceptable
b) Major & Minor Defects	G1	2.5

QUALITY SYSTEM CERTIFICATION

ISO 13485:2016
Certification : PPE Regulation (EU) 2016/425 by BSI

	100 pcs/ box				200 pcs/ box			
	S	M	L	XL	S	M	L	XL
Weight of empty dispenser (g)	54				82			
Weight of dispenser + Glove (g)	374	404	434	504	722	782	842	982
Weight of Carton (g)	308				326			
Weight of carton + dispenser (Kg)	4.0	4.3	4.6	5.3	7.5	8.1	8.7	10.1
Dimension of dispenser	100pcs / box : 237mm X 125mm X 55mm				200 pcs/box: 237mm X 125mm X 90mm			
Dimension of Carton:	100pcs/box:300mm X 489mm X 131mm				200 pcs/box: 475mm X 489mm X 131mm			

香港九龍觀塘鴻圖道 43 號 鴻達工業大廈 11 樓 5 室
Room 5, 11 / F, Hongda Industrial Building, 43 Hongtu Road, Kwun Tong, Kowloon, Hong Kong
URL: www.eco-select.com.cn Tel.: (852) 2330 6228 Fax: (852) 2330 6366

	100pcs /box
Number of carton per 20 footer container	1505
Number of carton per 40 footer container	3545

Country of Origin:

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Certificate Of CE(MDD) Notification

CERTIFICATE
OF
CE (MDD) NOTIFICATION

Ref. No.: CH 2468-2013
Date: 11/12/2013

Order No.: CH 2054-2013

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: [redacted]

[redacted] 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 above, 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 06/12/2013 in compliance with the European Council Directive 93/42/EEC and 2007/47/EC - article 14 requirements.

CLASS I MEDICAL DEVICE(S): PLEASE SEE ANNEX A - LIST OF DEVICES (1 PAGE, 4 DEVICES)

As of the 07/12/2013, 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.

OBELIS S.A.
Registered address
Bd Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

Mr. G. Ekoyem CEO
Obelis sa
date & stamp

CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES
17-12-2013
KAMER VOOR HANDEL EN NIJVERHEID VAN BRUSSEL

Brussels Enterprise
Commerce & Industry
date & stamp

SEEN
by the Brussels Chamber of Commerce
17 DEC. 2013
Brussels, the

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

Registered Address: Bd. Général Wahis 53 - 1030 Brussels | Registered Office Address: Av. de Tervueren 34 B44 - 1040 Brussels - Belgium
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CE

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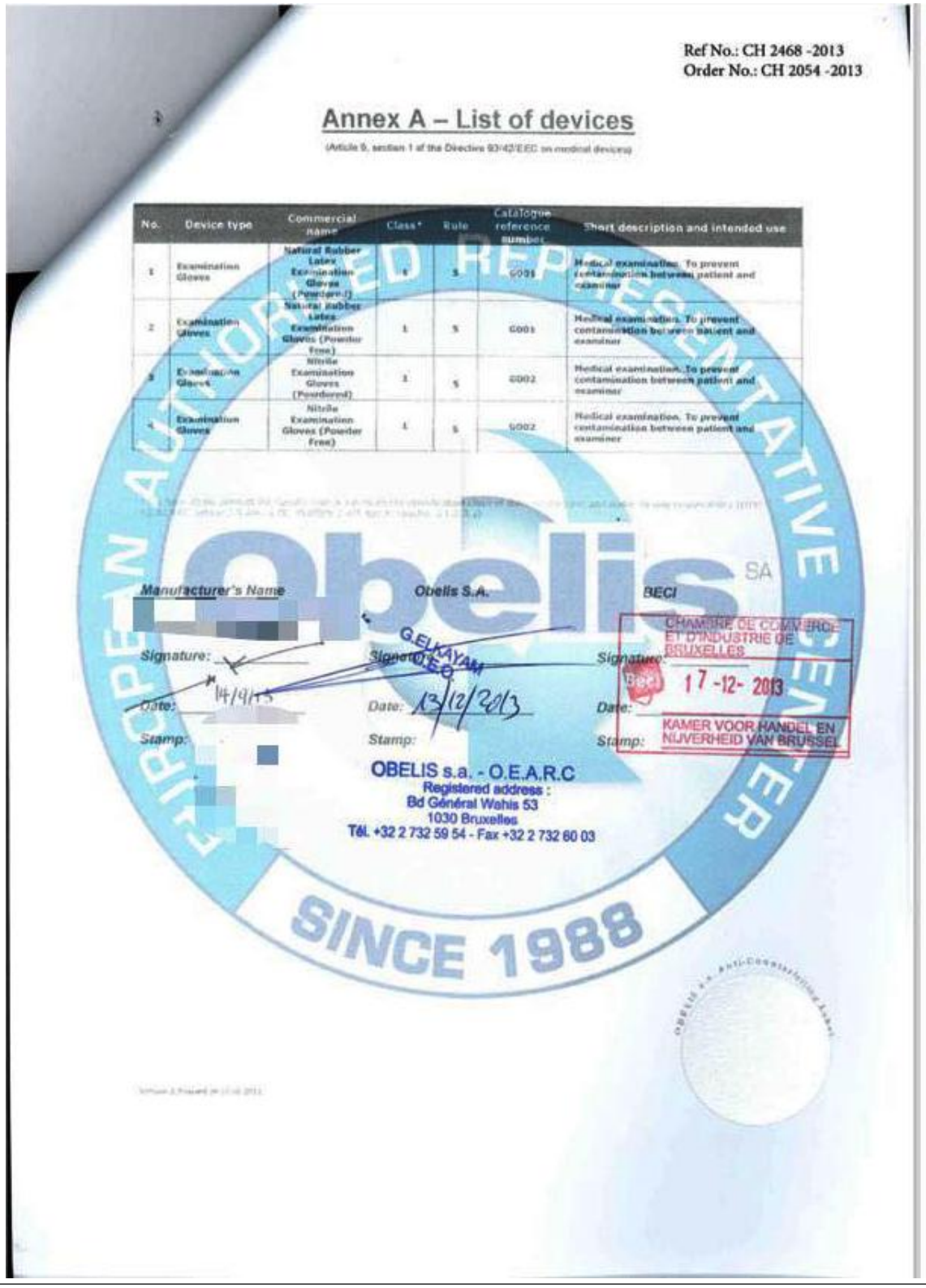

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Annex A – List of devices

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

No.	Device type	Commercial name	Class*	Rule	CaTaTogue reference number	Short description and intended use
1	Examination Gloves	Natural Rubber Latex Examination Gloves (Powdered)	1	1	G001	Medical examination. To prevent contamination between patient and examiner
2	Examination Gloves	Natural Rubber Latex Examination Gloves (Powder Free)	1	1	G001	Medical examination. To prevent contamination between patient and examiner
3	Examination Gloves	Nitrile Examination Gloves (Powdered)	1	1	G002	Medical examination. To prevent contamination between patient and examiner
4	Examination Gloves	Nitrile Examination Gloves (Powder Free)	1	1	G002	Medical examination. To prevent contamination between patient and examiner

Manufacturer's Name: [redacted]
Signature: [redacted]
Date: 14/9/13
Stamp: [redacted]

Obelis S.A.
Signature: GELKAYAM O.E.O
Date: 13/12/2013
Stamp: OBELIS s.a. - O.E.A.R.C
Registered address :
Bd Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

BECI
Signature:
Date: 17-12-2013
Stamp: CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES
KAMER VOOR HANDEL EN NIJVERHEID VAN BRUSSEL

EUROPEAN AUTHORISED REPRESENTATIVE
Obelis SA
SINCE 1988

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ISO 9001:2015

CARE Certification International

2018 2019 2020 Valid with sticker ONLY

Certificate No. : MYQ6183893

This certificate has been

Awarded to

[redacted]

Which is located at

[redacted]

On Standard

ISO 9001 : 2015

Which the organization stated above had been assessed and found to be in accordance with the requirements of international Quality Management System.

Under the Scope of

PROVISION OF INDUSTRIES GLOVE SUPPLY SERVICE.

Original Issued Date	:	**25th June 2015**
Effective Date	:	**20th June 2018**
Expiration Date	:	**24th June 2021**

This certificate will be null and void if at any circumstances the compliance towards the standards of ISO 17021 is not fulfilled. The compliance of the standards stated above will be indicated by the labelling on the right corner indicating the year of assessment. The validity of the certificate can also be traced to the audit report generated for each every assessment or through our website www.carecert.net

STANDARDS MALAYSIA ACCREDITED CERTIFICATION BODY

QS 02032013 CB 13

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

Fleming Teo
Managing Director
CARE Certification International (M) Sdn. Bhd.

CARE Certification International (M) Sdn. Bhd.
No. 3-16, IOI Boulevard, Jalan Kenari 6, Bandar Puchong Jaya, 47170 Puchong, Selangor Darul Ehsan, Malaysia.

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