Obelis SA
EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

EUROPEAN RESPONSIBLE PERSON REPRESENTER Obelis SINCE 1998

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,

CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES
27 JAN
KAMER VOOR HANDEL EN NIJVERHEID VAN BRUSSEL

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

Obelis s.a.
Registered Address :
Bld Général Wahis 53
1030 Bruxelles
+32 2

Brussels Enterprise
Commerce & Industry
date & stamp

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 I Registered Office Address: Av. de Tervueren 34 B44 - 1040 Brussels - Belgium
T: + 32 (0) 2 732 5954 I F: + 32 (0) 2 732 6003 I Email: mail@obelis.net I Website: www.obelis.net

This is to certify that the signature appears on this document/Certificate/Marriage Certificate/Birth/Death Certificate is that of PETER OOI SU SENG who is Notary Public
The Ministry of Foreign Affairs, Malaysia is not responsible of the accuracy of the information contained therein.

MINISTRY OF FOREIGN AFFAIRS MALAYSIA

Mohd Tarmizi Mohd Taib
Consular Officer
Consular Division
Ministry of Foreign Affairs
Putrajaya Malaysia

17 FEB 2020

CERTIFIED TRUE COPY

NOTARY PUBLIC
NOTARI AWAM
PETER OOI SU SENG
MUAR
MALAYSIA

14 FEB 2020

17 FEB 2020

MINISTRY OF FOREIGN AFFAIRS MALAYSIA VISA

ĐẠI SỨ QUÁN NƯỚC CHXHCN VIỆT NAM
TẠI MA-LAI-XI-A
CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

1. Quốc gia ..... **Việt Nam** .....
Country

Giấy tờ, tài liệu này
This public document

2. do Ông (Bà) ..... **Mohd Tarmizi Mohd Taib** ..... ký
has been signed by

3. với chức danh ..... **Lãnh sự** .....
acting in the capacity of

4. và con dấu của ..... **Cục Lãnh sự, Bộ Ngoại giao Ma-lai-xi-a**
bears the seal/stamp of

.....

được chứng nhận / hợp pháp hóa lãnh sự
Certified

5. tại ..... **Ma-lai-xi-a** .... 6. ngày ..... **18 / 2 / 2020**
at *the*

7. Cơ quan cấp ..... **Đại sứ quán nước CHXHCN Việt Nam**
by

8. Số ..... **30** ..../... **2020**
N°

Ký tên và đóng dấu
Signature and seal/stamp
Tham tán

Nguyễn Hồng Sơn

C.H.X.H.C.N VIỆT NAM ĐẠI SỨ QUÁN MALAIXIA

Order No. JP 3593-2014
Ref. No. JP 3621-2014

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 Obelis S.A.

Tan Sin Lian Industries Sdn. Bhd.

Signature: _____ *Signature:* _____ *Signature:* _____

Date: 09/12/2014 *Date:* 12/01/2015 *Date:* _____

Stamp: TAN SIN LIAN INDUSTRIES SDN. BHD. (Co-approved) *Stamp:* S. FERRETTI C.C.O. *Stamp:*

BECI CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES 22-01-2015

Obelis s.a.
Registered Agent
Bld Général Wahis 53
1030 Bruxelles
TEL +32 2 732 59 54 FAX +32 2 732 60 03

This is to certify that the signature appears on this document/Certificate/Marriage Certificate/Birth/Death Certificate is that of PETER OOI SU SENG who is Notary Public
The Ministry of Foreign Affairs, Malaysia is not responsible of the accuracy of the information contained therein.

MINISTRY OF FOREIGN AFFAIRS MALAYSIA

Mohd Tarmizi Mohd Taib
Consular Officer
Consular Division
Ministry of Foreign Affairs
Putrajaya Malaysia

17 FEB 2020

CERTIFIED TRUE COPY

NOTARY PUBLIC
NOTARI AWAM
PETER OOI SU SENG
MUAR
MALAYSIA

14 FEB 2020

17 FEB 2020

MINISTRY OF FOREIGN AFFAIRS MALAYSIA

ĐẠI SỨ QUÁN NƯỚC CHXHCN VIỆT NAM
TẠI MA-LAI-XI-A
CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

1. Quốc gia ..... **Việt Nam** .....
Country

Giấy tờ, tài liệu này
This public document

2. do Ông (Bà) ..... **Mohd Tarmizi Mohd Taib** ..... ký
has been signed by

3. với chức danh ..... **Lãnh sự** .....
acting in the capacity of

4. và con dấu của ..... **Cục Lãnh sự, Bộ Ngoại giao Ma-lai-xi-a**
bears the seal/stamp of

.....

được chứng nhận / hợp pháp hóa lãnh sự
Certified

5. tại ..... **Ma-lai-xi-a** .... 6. ngày **18 2 2020**
at *the*

7. Cơ quan cấp ..... **Đại sứ quán nước CHXHCN Việt Nam**
by

8. Số ..... **30** ..... / **2020**
N°

Ký tên và đóng dấu
Signature and seal/stamp
Tham tán

Nguyễn Hồng Sơn

C.H.X.H.C.N VIỆT NAM
ĐẠI SỨ QUÁN ★ MA LAI XI A