



TOSOH CORPORATION

TOSOH



Declaration

I hereby make a declaration that the attached certificates are copy of the original documents.

- (1) Certificate issued by Soichiro Isobe, Director, Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare
- (2) Certificate issued by Mamoru Yano, Secretary General, Overseas Medical Equipment Technical Assistants (OMETA)
- (3) Certificate issued by Katsuhiko Mochizuki, Senior Managing Director, Japan Association of Clinical Reagents Industries
- (4) Announcement for Certificate issued by Japan's association to export Calibrator, Control Serum and Medium for In-vitro Diagnostics Reagents issued by Soichiro Isobe, Director, Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare

May 25, 2017

Masayuki Yamada
Senior Vice President
Senior General Manager
Bioscience Division
Tosoh Corporation

OMETA

Non Profit Organization

Overseas Medical Equipment Technical Assistants

1-58-10-173, Yoyogi, Shibuya-ku, Tokyo, 151-0053 Japan

Tel: +81-3-3372-1793 Fax: +81-3-3372-1797 <http://www.ometa.or.jp>

January 6, 2016

To whom it may concern,

CERTIFICATE

We, Non Profit Organization Overseas Medical Equipment Technical Assistants (OMETA), hereby certify that the products named as shown under are manufactured by TOSOH CORPORATION, 3-8-2, Shiba, Minato-ku, Tokyo 105-8623, Japan.

The products are not applicable as medical devices which are defined under the Pharmaceuticals, Medical devices and Other Therapeutic Products Act of Japan.

Therefore, they are not necessary to be produced under the supervision of The Ministry of Health, Labour and Welfare in Japan as stipulated in the Pharmaceuticals, Medical devices and Other Therapeutic Products Act of Japan, and they are sold domestically and in foreign countries freely.

Products :
1. AIA-PACK SAMPLE TREATMENT CUP
2. AIA-PACK DETECTOR STANDARDIZATION TEST CUP

Manufacturing Site :
TOSOH AIA, INC.
2, Iwasekoshi-machi, Toyama, Toyama 931-8510, Japan

Non Profit Organization

Overseas Medical Equipment Technical Assistants (OMETA)


Mamoru Yano
Secretary General

CTF-I-1617

1528E



MINISTRY OF HEALTH, LABOUR AND WELFARE
GOVERNMENT OF JAPAN
2-2, KASUMIGASEKI 1-CHOME, CHIYODA-KU, TOKYO 100-8916

CERTIFICATE

It is hereby certified that the following in vitro diagnostic exported by Tosoh Corporation, 4560, Kaisei-cho, Shunan, Yamaguchi 746-8501, Japan is manufactured under our supervision as stipulated in the Pharmaceuticals, Medical devices and Other Therapeutic Products Act of Japan.

Product : ST AIA-PACK AFP

Component Reagents :

ST AIA-PACK AFP
AIA-PACK AFP CALIBRATOR SET
AIA-PACK AFP SAMPLE DILUTING SOLUTION
AIA-PACK AFP CALIBRATION VERIFICATION TEST SET
AIA-PACK SUBSTRATE SET II
AIA-PACK WASH CONCENTRATE
AIA-PACK DILUENT CONCENTRATE

Name of the Office for General Marketing Manager:TOSOH CORPORATION Headquarters
Address: 3-8-2, Shiba, Minato-ku, Tokyo 105-8623, Japan

Licence Number:13E1X80174

Name of Manufacturing Site : TOSOH AIA, INC.

Address : 2, Iwasekoshi-machi, Toyama, Toyama 931-8510, Japan

No. 2235

TOKYO, date AUG. 22. 2016

磯部 総一郎



Soichiro Isobe
Director, Medical Device Evaluation Division
Pharmaceutical Safety and Environmental Health Bureau
Ministry of Health, Labour and Welfare

Registered No. 1402 of 2017

NOTARIAL CERTIFICATE

This is to certify that Miki Nakajima, an agent of Masayuki Yamada, Senior Vice President, Senior General Manager, Bioscience Division of Tosoh Corporation, has stated in my very presence that said Masayuki Yamada acknowledged himself to have signed to the attached document.

Dated this 8th day of June, 2017.



Hideki Niikura 

Hideki Niikura

Notary, Shiba Notary's Office

Tokyo Legal Affairs Bureau

19-14, 3-chome, Nishishimbashi

Minato-ku, Tokyo, Japan.



平成 29 年 登簿 第

1402 号

認

証

東ソー株式会社

上席執行役員 バイオサイエンス事業部長

山田 正幸 (Masayuki Yamada)

の代理人中島美希は、本公証人の面前において、上記本人が別紙書面に署名したことを自認している旨陳述した。

よって、これを認証する。

平成 29 年 6 月 8 日、本公証人役場において

東京都港区西新橋三丁目19番14号

東京法務局所属

公証人

Notary

新倉 英樹



Hideki NIKURA

総公証 No 143537 号

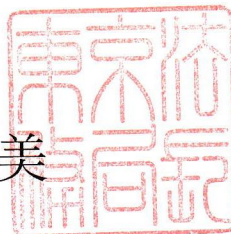
証 明

上記署名は、東京法務局所属公証人の署名に相違ないものであり、かつ、その押印は、真実のものであることを証明する。

平成 29 年 6 月 8 日

東京法務局長

秋山 仁美



CERTIFICATE

This is to certify that the signature affixed above has been provided by Notary, duly authorized by the Tokyo Legal Affairs Bureau and that the Official Seal appearing on the same is genuine.

Date June 8, 2017

Hitomi AKIYAMA

Director of the Tokyo Legal Affairs Bureau

For legalization by the foreign consul in Japan, this is to certify that the Seal affixed hereto is genuine.

Date June 8, 2017

T. TANAKA

Toshie TANAKA

Tokyo,

Official

Ministry of Foreign Affairs





ĐẠI SỨ QUÁN CHXHCN VIỆT NAM TẠI NHẬT BẢN
EMBASSY OF THE S.R. OF VIETNAM IN JAPAN
CHỨNG NHẬN/HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

- Quốc gia: VIỆT NAM
Country: Vietnam
 - Do ông (bà):
Has been signed by:
 - Với chức danh:
Acting in the capacity of:
 - Và con dấu của:
Bears the seal/stamp of:
 - Tại: Tô-ki-ô
At: Tokyo
 - Cơ quan cấp:
By:
 - Số: **15/06/17-38**
Nº
- Giấy tờ, tài liệu này
This public document
- TOSHIE TANAKA** ký
- CÔNG CHỨC
OFFICIAL
- BỘ NGOẠI GIAO NHẬT BẢN
MINISTRY OF FOREIGN AFFAIRS OF JAPAN.
- được chứng nhận/hợp pháp hóa lãnh sự
Certified
6. Ngày 15/06/2017
The (dd/mm/yyyy)
- ĐẠI SỨ QUÁN CHXHCN VIỆT NAM TẠI NHẬT BẢN
EMBASSY OF THE S.R. OF VIETNAM IN JAPAN

707041091

TL. Đại sứ/For the Ambassador
Bí thư thứ Nhất/First Secretary



NGUYỄN AN TIẾN.