



DNV·GL

# MANAGEMENT SYSTEM CERTIFICATE

Certificate No.:  
02854-2016-AQ-KOB-RvA/JAB

Initial certification date:  
14 September, 2016

Valid:  
21 August, 2018 - 21 August, 2021

This is to certify that the management system of

## **Enagic International Co., Ltd.**

Osaka factory: 1-40-1 Hoshidakita, Katano, Osaka Pref. 576-0017, Japan

and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:  
**ISO 9001:2015 = JIS Q 9001:2015**

This certificate is valid for the following scope:

**Design, Development, Manufacture, Distribution, Repair and Maintenance of  
Electrolysis Water Generators, Water Purifiers, and Water Processing  
Machines of Functional Water Generator for Medical and General Use**

Place and date:  
Kobe, 23 August, 2018



The RvA is a signatory to the IAF MLA

For the issuing office:  
DNV GL - Business Assurance  
Sannomiya Chuo Bldg. 9th Floor,  
4-2-20, Goko-dori, Chuo-ku, Kobe  
651-0087

Naoki Maeda  
Management Representative



# MANAGEMENT SYSTEM CERTIFICATE

Certificate No.:  
01306-2005-AE-KOB-RvA/JAB

Initial certification date:  
18 May, 2005

Valid:  
14 June, 2019 – 13 June, 2022

This is to certify that the management system of

## **Enagic International Co., Ltd.**

Osaka factory: 1-40-1 Hoshidakita, Katano, Osaka Pref. 576-0017, Japan

and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Environmental Management System standard:  
**ISO 14001:2015 = JIS Q 14001:2015**

This certificate is valid for the following scope:

**Design, Development, Manufacture, Distribution, Repair and Maintenance of  
Electrolysis Water Generators, Water Purifiers, and Water Processing  
Machines of Functional Water Generator for Medical and General Use**

Place and date:  
Kobe, 14 June, 2019



The RvA is a signatory to the IAF MLA

For the issuing office:  
DNV GL - Business Assurance  
Sannomiya Chuo Bldg. 9th Floor,  
4-2-20, Goko-dori, Chuo-ku, Kobe  
651-0087

Naoki Maeda  
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

ACCREDITED UNIT: DNV GL Business Assurance Japan K.K., Sannomiya Chuo Bldg. 9th Floor, 4-2-20, Goko-dori, Chuo-ku, Kobe 651-0087.  
TEL: 81782911321. <http://assurance.dnvgl.com>

DNV GL Business Assurance B.V., ZWOLSEWEG 1, 2994 LB, BARENDRECHT, NETHERLAND. TEL: +31102922689. [www.dnvba.com](http://www.dnvba.com)

# Management System Certificate

Certificate No.:  
240698-2017-AQ-JPN-NA-PS Rev. 1.0

Project No.:  
PRJC-17934-2007-MSA-JPN

Initial Certification Date:  
02 August 2017

Valid Until:  
27 April 2020

This is to certify that the management system of:

**Enagic International Co., Ltd.**

1-40-1 Hoshidakita, Katano City, Osaka Pref. 576-0017, Japan

With sites as listed overleaf.

Complies with the requirements of:

**ISO 13485:2016**

The Certificate is valid for the following scope:

**Design, Manufacture, Service and Distribution of Electrolysis Water Generators for Medical Use**

**มาตรฐานรับรอง  
การผลิตเครื่องมือแพทย์  
ISO 13485**

Place and Date:  
Høvik, 07 February 2019



For:  
DNV GL PRESAFE AS

*Tone Kolpus*

**Tone Kolpus**

The Certificate has been digitally signed.  
See [www.presafe.com/digital\\_signatures](http://www.presafe.com/digital_signatures) for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.



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 ENAGIC INC., 1-40-1 Hoshidakita, Katano City, Osaka Pref., 576-0017, Japan is a medical device marketing authorization holder licensed in accordance with the provision of Paragraph 1, Article 12 of the Pharmaceutical Affairs Law of Japan.

Name of the Marketing Authorization Holder: ENAGIC INC.

Address: 1-40-1 Hoshidakita, Katano City, Osaka Pref., 576-0017, Japan

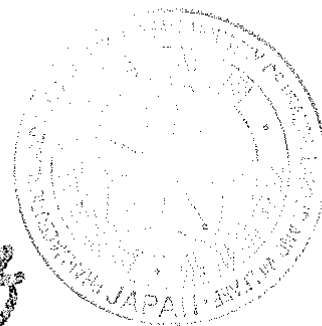
License Number: 2 7 B 2 X 0 0 0 7 0

มาตรฐานรับรอง  
การผลิตและจัดจำหน่ายเครื่องมือแพทย์  
รับรองโดย กระทรวงสาธารณสุข ประเทศญี่ปุ่น

No. 3262

Tokyo, date 9. 11. 2010

飯不登美子



Tomiko Tawaragi  
Director, Safety Division  
Pharmaceutical and Food Safety Bureau  
Ministry of Health, Labour and Welfare



許可番号 27BZ006010



医療機器製造業許可証

氏 名 株式会社エナジック

**English Translated**  
**Medical Device Manufacturing license**  
Issued by Osaka Prefecture. License  
Number: 27BZ006010

製造所の名称 株式会社エナジック

製造所の所在地 大阪府交野市星田北一丁目40番1号

許可の区分 医療機器 一般

薬事法第13条第1項の規定により許可された医療機器製造業者であることを  
証明する。

平成 23 年 10 月 5 日

大阪府知事

橋下

徹



有効期間 平成 23 年 12 月 5 日から

平成 28 年 12 月 4 日まで

2722377000534

ใบอนุญาตการผลิตเครื่องมือแพทย์  
รับรองโดย เมืองโอซาก้า ประเทศญี่ปุ่น

# Water Quality Association Gold Seal Certificate

Enagic USA

4115 Spencer St.  
Torrance, CA United States  
Facility: Enagic Factory

Certification Date: March 16, 2015

Authorized By: *Jana P. Undesser*  
Pauli Undesser  
Deputy Executive Director



Water Quality Association  
4151 Naperville Road  
Lisle, IL 60532, USA



Revision: 02/19/2015

FORM.12046

This Certificate, or any part thereof, may not be used in a misleading manner and validation of its use is contingent upon the Official WQA web -listing.

## Water Quality Association Official Gold Seal Listing

Granted to the following company:	Enagic USA 4115 Spencer St. Torrance, CA 90503 United States
For the Facility Located at:	Enagic Factory 1-40-1, Hoshida-Kita Osaka, Japan

The WQA Gold Seal Certification Department has issued certification for the following model(s) to the standard(s) below. Only models that appear in the official listing are authorized to bear the WQA Gold Seal.

NSF/ANSI 42 (10/16/2014): Drinking Water Treatment Units, Aesthetic Effects is within WQA's ANSI and SCC approved scope of accreditation under the Drinking Water Treatment Units Scheme

Leveluk Leveluk K8

Leveluk SD501 TYH-401

CSA B483.1 (12/01/2007): Drinking Water Treatment Systems is within WQA's ANSI and SCC approved scope of accreditation under the Drinking Water Treatment Units Scheme

Leveluk Leveluk K8

Leveluk SD501 TYH-401

NSF/ANSI 372 (07/31/2011) (Previously WQA ORD0902, NSF/ANSI 61, Annex G, California AB 1953) is within WQA's ANSI and SCC approved scope of accreditation under the Drinking Water System Components - Lead Content Scheme

Leveluk Leveluk K8

Leveluk SD501 TYH-401

NSF/ANSI 18 (08/08/2012): Manual Food & Beverage Dispensing Equipment is within WQA's ANSI and SCC approved scope of accreditation under the General Scheme

Leveluk Leveluk K8

Leveluk SD-501 TYH-401

Notice: To request any changes to the certified model(s), please request a Change to Certified Product (CCP) form. Examples include any change to the wetted parts or formulations such as supplier or material types, literature, or a change in company name. This list is not all inclusive. Failure to submit documentation regarding changes may result in non-compliance with the standard(s) as well as de-listing of the affected models.



No.: R130110035

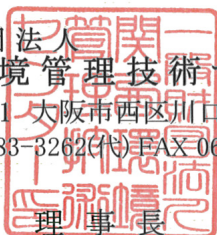
Date: 2013/1/16

## 放射能による表面非汚染検査結果報告書

Inspection Report of  
Non-radioactive Surface Contamination

株式会社エナジック 殿

(Client name) Enagic, Inc.

一般財団法人  
関西環境管理技術センター  
〒550-0021 大阪市西区川口2-9-10  
TEL 06-6583-3262(代) FAX 06-6583-3274

理事長 内藤 昇

General Incorporated Foundation  
Environmental Management  
and Technology Center  
(EMATEC)

2-9-10, Kawaguchi, Nishiku, Osaka, 550-0021 Japan

President Signature

## 検査結果 Results of Inspection

ご依頼の製品を検査した結果、放射能による表面汚染はありません。

WE HEREBY CONFIRM THAT THE PRODUCT DESCRIBED BELOW HAS BEEN  
INSPECTED AND IS FREE OF SURFACE RADIOACTIVE CONTAMINATION.

日時	Date of Inspection:	2013/1/15 15:30		
場所	Place:	関西環境管理技術センター内(大阪市) Osaka, Japan		
測定値	Measured values:	平均値	Average value	27 (cps)
		最大値	Maximum value	28 (cps)
バックグラウンド値	Background values:	平均値	Average value	27 (cps)
		最大値	Maximum value	28 (cps)

検査品名	Product Name:	レベラック スーパー 501 ,	LeveLuk Super 501
品番	Stock Number:	TYH-501/TYH-502	
サイズ	Size:	250mm×352mm×352mm	
備考	Remarks:	Lot.No.19101725	

測定機器	Measuring Device	:シンチレーション サーベイメーター, Scintillation Survey Meter (Type: Aloka TCS-172B)
		:GM サーベイメーター, GM Survey Meter (Type: Aloka TGS-121)

測定方法 Measuring Method:

シンチレーションサーベイメーターのプローブ先端を検査品表面に近づけて表面を測定。

Surface contamination inspection were measured by bringing the probe tip of the survey meter in close to the product surface.

時定数 Time constant: 10 sec, 測定回数 Number of measurements: 8

備考 Remarks:

測定値にはバックグラウンド値が含まれているので、測定対象物の測定値がバックグラウンド値と同等であるとき、表面汚染なしと判定する。

As measured values include background values, when radiation dose of measured object is equal to background value, we judge that there is no surface radioactive contamination.



# United States of America

United States Patent and Trademark Office

## KANGEN WATER

**Reg. No. 4,063,154**

**Registered Nov. 29, 2011**

**Int. Cl.: 11**

**TRADEMARK**

**PRINCIPAL REGISTER**

ENAGIC CO., LTD. (JAPAN CORPORATION)  
7F ECHIZENYA BLDG 1-1-6 KYOBASHI CHUO-KU  
TOKYO, JAPAN

FOR: ELECTROLYTIC WATER GENERATORS FOR ELECTRICALLY DECOMPOSING TAP WATER TO GENERATE ELECTROLYTIC WATER AND FOR REMOVING CHLORINE ODOR FROM TAP WATER, IN CLASS 11 (U.S. CLS. 13, 21, 23, 31 AND 34).

FIRST USE 6-23-2005; IN COMMERCE 6-23-2005.

THE MARK CONSISTS OF STANDARD CHARACTERS WITHOUT CLAIM TO ANY PARTICULAR FONT, STYLE, SIZE, OR COLOR.

OWNER OF U.S. REG. NO. 2,990,706.

NO CLAIM IS MADE TO THE EXCLUSIVE RIGHT TO USE "WATER", APART FROM THE MARK AS SHOWN.

THE ENGLISH TRANSLATION OF KANGEN IN THE MARK IS REDUCTION OR DEOXIDATION.

SEC. 2(F).

SER. NO. 85-304,673, FILED 4-26-2011.

THEODORE MCBRIDE, EXAMINING ATTORNEY



*David J. Kypos*

Director of the United States Patent and Trademark Office





# Certification of Patent

4747092

Patent Number

Invention Title     Distributor Management System

Patentee             Enagic Co., Ltd  
Echizenya Bldg. 7F, 1-1-6 Kyobashi  
Chuo-ku, Tokyo 104-0031

Inventor             Hironari Ohshiro

Application Number     2006-512499

Filing Date             April 8, 2005

Registration Date         May 20, 2011

This is to certify that the patent is registered on the register  
of the Japan Patent Office.

Commissioner, Japan Patent Office

岩井良行

