



Created by
Compliance Department

Compliance Guideline

Medical Device & Medical Claims

Enagic (Malaysia) Sdn Bhd
(201101042983) (Direct Sales License No.: AJL 931978)



Introduction

Medical Device Act 2012

Enagic (Malaysia) Sdn Bhd is **not a registered medical device in Malaysia.**

Therefore, it is **prohibited** for anyone to

- **advertise Enagic products** as a **medical device in Malaysia.**
- **make any therapeutic, curative or medical claims** of the products and/or water produced by Enagic products.



1. Medical Device

Section 5 – Requirement for registration of medical device

(1) No medical device shall be imported, exported or placed in the market unless the medical device is registered under this Act.

Section 15 – Requirement for establishment license (License & Permit)

(1) No establishment shall import, export or place in the market any registered medical device unless it holds an establishment license granted under this Act.



1. Medical Device

Section 44 – Advertising

(1) No person shall advertise a medical device unless the medical device has been registered and complied with the requirements of this Act.

(2) No person shall make any misleading or fraudulent claims in respect of a medical device in any advertisement.



1. Medical Device

What are the instructions provided by the Medical Device Authority (MDA)?

- MDA clearly **prohibits** these certificates to be used in Malaysia:
 - **Japanese Association of Preventative Medicine for Adult Disease**
 - **Ministry of Health, Labour and Welfare Government of Japan**; 'License Number: 27B2X00070' and 'License Number: 27BZ006010'
 - **ISO 13485** – design, manufacture, sales, servicing and distribution of electrolysis water generators for medical use.



1. Medical Device

What are the **penalty** of the offence?

- **Section 44 – Advertising**

(3) Any person who contravenes subsection (1) or (2) commits an offence and shall, on conviction, be liable to a **fine not exceeding three hundred thousand ringgit** or to **imprisonment for a term not exceeding three years** or to **both**.



2. Medical Claims

No distributors are allowed to make therapeutic and medical claims or curative properties about the products and/or water produced by Enagic products may be made.

What are the terms that **prohibited** to be used?

- diagnose
- alleviate
- cure
- prevent
- relieve
- treat any medical condition, disease, ailment or malady.



2. Medical Claims

Medicine (Advertisement & Sale) Act 1956

Section 3 – Prohibition of advertisement relating to certain diseases

(1) Subject to this Act, no person shall take any part in the publication of any advertisement referring to any article, or articles of any description, in terms which are calculated to lead to the use of that article or articles of that description as a medicine, an appliance or a remedy for the purpose of –



2. Medical Claims

- (a) prevention or treatment of the diseases and conditions of human beings as specified in the Schedule;
- (b) practising contraception among human beings;
- (c) improving the condition or functioning of the human kidney or heart, or improving the sexual function or sexual performance of human beings;
- (d) diagnosis of a disease as specified in the **Schedule**:



2. Medical Claims

Schedule:

- Diseases or defects of the kidney.
- Diseases or defects of the heart.
- Diabetes
- Epilepsy or fits.
- Paralysis.
- Tuberculosis.
- Asthma.
- Leprosy.
- Cancer.
- Deafness.
- Drug addiction.
- Hernia or rupture.
- Diseases of the eye.
- Hypertension.
- Mental disorder.
- Infertility.
- Frigidity
- Impairment of sexual function or impotency.
- Venereal disease.
- Nervous debility, or other complaint or infirmity, arising from or relating to sexual intercourse.



2. Medical Claims

Medicine (Advertisement & Sale) Act 1956

Section 4B – Advertisements of medicines to be approved

(1) No person shall take any part in the publication of any advertisement referring to any article, or articles of any description, in terms which are calculated to lead to the use of that article of that description as a medicine, an appliance or a remedy for the purpose of treatment or prevention of diseases or condition specified in subjection 3(1), unless such advertisement has been approved by the Medicine Advertisement Board.



2. Medical Claims

Medicine (Advertisement & Sale) Act 1956

Section 4B – Advertisements of medicines to be approved

(2) Any advertisement proposed to be published may be submitted to the Medicine Advertisement Board for approval in the manner provided for the regulations made under Section 7.



2. Medical Claims

What are the **example** of the offence?

Enagic
KANGEN
WATER SYSTEM
Anti-Oxidation/Micro-Clustering/Alkalinization
You Deserve the Best in Life!
Health and Wealth

Change Your Water..
Change Your Life..
The Original Energy Drink

DRINKING ALKALINE IONIZED WATER pH 8.5, 9.0 & 9.5
bermanfaat untuk mengembalikan tubuh dalam keadaan
biasa (alkali) sehingga dapat mencegah dan mempercepat
proses penyembuhan dari pelbagai jenis penyakit seperti:

- Diabetes
- Jantung
- Kanser
- Stroke
- Gout
- Gastrik
- Obesiti
- Penyakit Pencernaan
dan perist. Usus besar
- Alergi
- Migran
- Arthritis
- Asma
- Tekanan Darah Tinggi
- Kolestrol Tinggi
- Sakit Sendi
- Penyakit Kulit

Certified Medical Device and Only Alkaline Water Ionizer
in the World to Receive the Gold Seal Award by the WQA

**Revolutionize your
lifestyle with water!!**



2. Medical Claims

What are the
example of the offence?

Kangen Water™ Testimonial

Bill Powers' Throat Cancer Testimonial
From 7 months to live... to Cancer Free
May 2009 till December 2009
What I discovered about Kangen Water™ during my battle with cancer
Personal Victory by Bill Powers
It works for me. I am LIVING PROOF.

Testimoni Kanser Takak Bill Powers
Bebas Dari Kanser Hari-hari 3 bulan untuk hidup.. Kepada
Bebas Dari Kanser May 2009 hingga Desember 2009
Apa yang saya dapati tentang Kangen Water™ dalam pertempuran saya dengan kanser. Selama Perjuangan Saya Melawan Kanser. Sukses. Kemenangan. Terbukti. Oleh Bill Powers Kangen Water™ berkesan bagi saya. Saya merupakan BUKTI HIDUP.

Case 1
Many hospitals in Japan use Kangen Water™ pH2.5 Strong Acidic Water for treatment of various skin conditions, e.g. Psoriasis. Patients are advised to drink Kangen Water™ daily and used the strong acidic water to bath the affected areas. After 2 weeks, the viscles dried up. The Psoriasis was completely cleared without any relapse.

Kes 1
Banyak hospital di Jepun menggunakan Kangen Water™ pH2.5 Air berasid tinggi untuk rawatan pelbagai keadaan kulit, contohnya Psoriasis. Pesakit dinasihatkan supaya minum Air Kangen setiap hari dan menggunakan air berasid tinggi untuk dibasuhkan di bahagian yang terjejas. Selepas 2 minggu, ruam mulai kering dan masalah Psoriasis terhapus dengan.

CONDITIONS IMPROVED AFTER DRINKING KANGEN WATER™

After two weeks of treating daily with Strong Acidic Water (pH2.5)

Dr. Otto Warburg
Dr. Otto Warburg investigated the metabolism of tumors and the respiration of cells. 1931 Nobel Prize Winner in Cell Physiology or Medicine.
Dr. Otto Warburg menyiasat metabolisme tumor dan sel respirasi. 1931 Pemenang Hadiah Nobel dalam Fisiologi dan Perubatan.

Dr. Hiromi Shinya
M.D., Ph.D.
"I have a Kangen Water™ bottle in my New York medical office and this is the water I drink and give to my patients. In addition to filtering out pollutants this Kangen Water™ has strong reduction power and helps keep the body at an optimal alkaline water."
Professor of Surgery, Albert Einstein College of Medicine, Chief of Endoscopy Department, Beth Israel Medical Centre, New York City.
Developer of the Endoscope for use in Colonoscopy. Reviewed more than 370,000 cases for colonoscopies. His Treatment Protocol includes Kangen Water™.
"Saya mempunyai mesin Kangen Water™ di pejabat perubatan New York saya dan ini adalah air yang saya minum dan memberi kepada pesakit saya. Selain menjadi bahan pencuci, air Kangen Water™ mempunyai kuasa pengurangan kuat dan membantu menjaga badan pada air alkali yang optimum."
Professor Pembedahan, Kolej Perubatan Albert Einstein, KETUA JABATAN ENDOSKOPI, Pusat Perubatan Beth Israel, Bandar New York.
Pencipta Endoskop yang digunakan dalam Kolonoskopi. Telah melakukan 370,000 kolonoskopi. Protokol Rawatan beliau termasuk penggunaan Kangen Water™.

Acidosis
Acidosis (occurs when arterial pH is too low). It causes: Acidosis (berlaku apabila pH arteri adalah terlalu rendah). Ia menyebabkan:
* Premature Aging * Hormone Imbalance * High Blood Pressure * Heart Attacks * Stroke * High Cholesterol * Diabetes * Prostate Problems
* Perasaan Prematur * Ketidak Seimbangan Hormon * Tekanan Darah Tinggi * Rendah Daya Imun * Serangan Jantung * Strok * Kolesterol Tinggi * Kencing Manis * Masalah prostat

ASID PUNCA PENYAKIT
Tubuh kita dicipta bersifat alkali. Asid yang berlebihan didalam badan adalah punca segala penyakit. Asid dikeluarkan oleh perut untuk membantu penghadaman. Selain daripada perut, anggota badan yang lain tidak seharusnya terdapat asid.

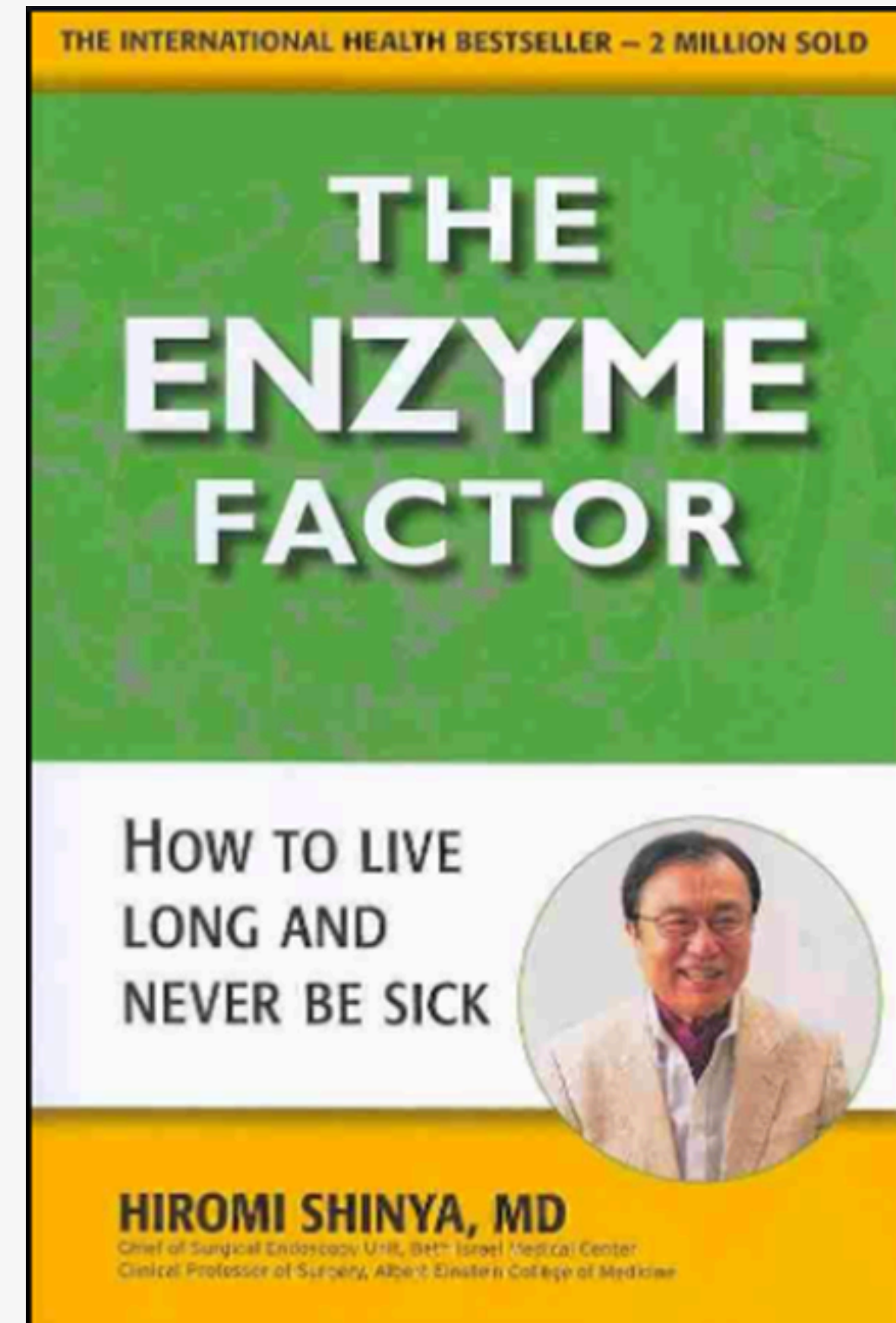
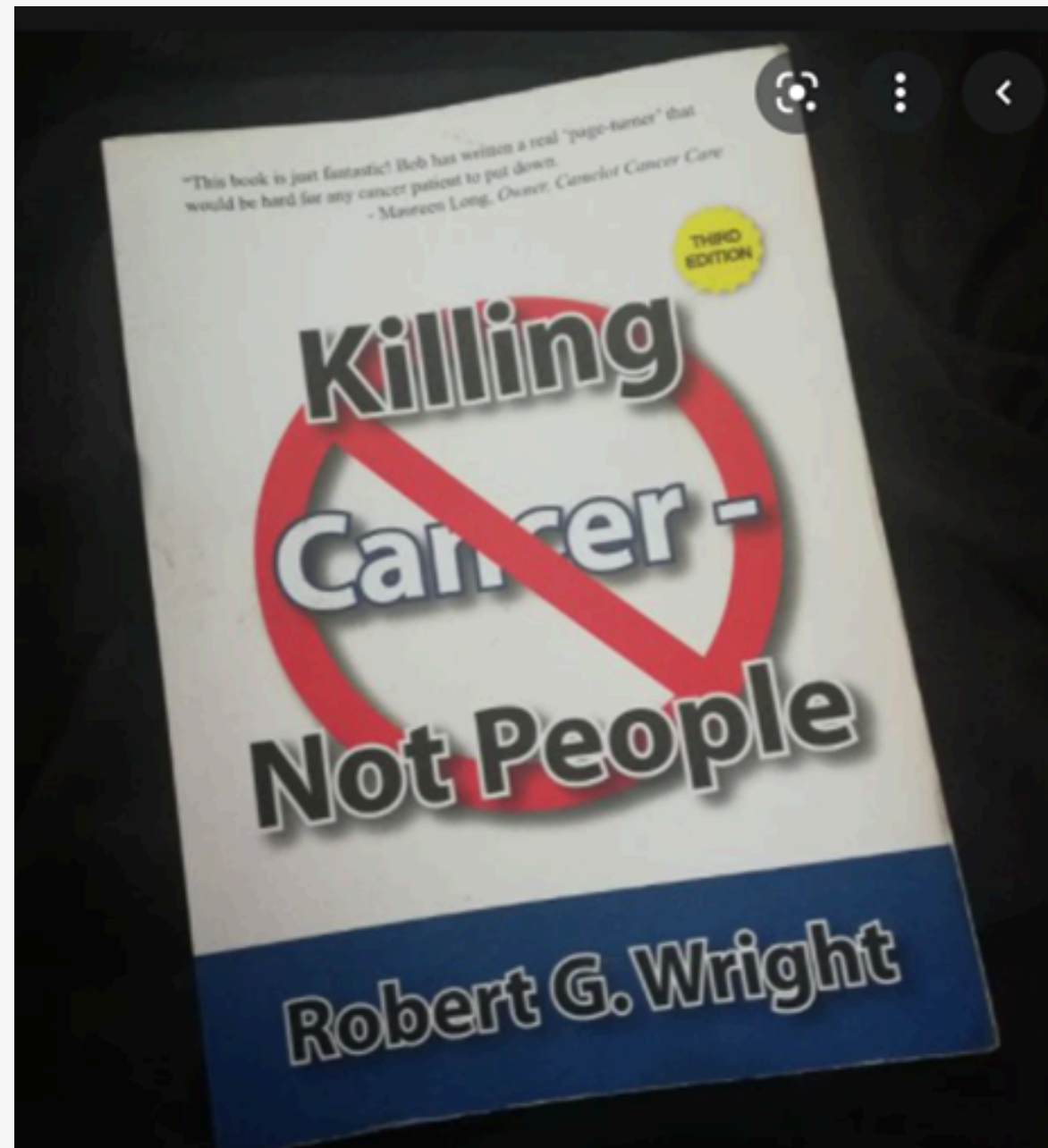
Perubahan pH dalam usus dan feses
The change in the Colon Regarding the change of pH value

THE ENZYME FACTOR
THE MICROBE FACTOR



2. Medical Claims

What are the
example of the offence?





2. Medical Claims

What are the **penalty** of the offence?

- **Section 5. Provisions as to offences under sections 3, 4, 4A and 4B.**

(1) If any person contravenes any of the provisions of sections 3, 4, 4A and 4B, he shall, subject to the provisions of this Act, be liable on summary conviction—

(a) in the case of a first conviction, to a **fine not exceeding three thousand ringgit** or to **imprisonment for any term not exceeding one year** or to **both**; and

(b) in the case of a subsequent conviction, to a **fine not exceeding five thousand ringgit**, or to **imprisonment for a term not exceeding two years**, or to **both**.



3. Water produced by Enagic

Enagic **does not** recommend the **(1) consumption of Strong Acidic Water (pH 2.5)** and **Strong Kangen Water (pH 11.5)**.

Enagic adheres to the **National Standard for Drinking Water Quality (MOH)** and **Guidelines for Drinking-water Quality (WHO)**.



3. Water produced by Enagic

National Standard for Drinking Water Quality (MOH)

Section 3 – Quality Requirements

3.2 Drinking Water Quality Standards

3.2.1 Drinking water must be clear, and does not have objectionable taste, colour and odour. It must be pleasant to drink and free from all harmful organisms, chemical substances and radionuclides in amounts, which could constitute a hard to the health of the consumer.



3. Water produced by Enagic

National Standard for Drinking Water Quality (MOH)

Section 3 – Quality Requirements

3.2 Drinking Water Quality Standards

3.2.2 The quality of drinking water is measured in terms of its microbiological, physical, chemical and radioactivity characteristics. **Table 2** lists some of these **characteristics** and **constituents** with their **recommended standards**, which shall not be exceeded for maximum protection of the consumer.



3. Water produced by Enagic

National Standard for Drinking Water Quality (MOH)

Section 3 – Quality Requirements

3.2 Drinking Water Quality Standards

	<u>PHYSICAL:</u>							
9	TURBIDITY	5 NTU	W	W	M	2Y	WHO2	
10	COLOUR	15 TCU	W	W	M	2Y	WHO2	
11	pH	6.5 – 9.0	W	W	M	2Y	MAL	
12	FREE RESIDUAL CHLORINE	0.2 – 5.0	W	W	M	2Y	WHO1	
13	COMBINED RESIDUAL CHLORINE	NOT LESS THAN 1.0	W	W	M	2Y	MAL1990	
14	MONOCHLORAMINE	3	WN	WN	WN	WN	WHO2	



3. Water produced by Enagic

Guidelines for Drinking-water Quality (WHO)

pH in Drinking water

Effects on humans

Exposure to extreme pH values results in irritation to the eyes, skin, and mucous membranes. Eye irritation and exacerbation of skin disorders have been associated with pH values greater than 11. In addition, solutions of pH 10 – 12.5 have been reported to cause hair fibres to swell. In sensitive individuals, gastrointestinal irritation may also occur.



3. Water produced by Enagic

Guidelines for Drinking-water Quality (WHO)

pH in Drinking water

Effects on humans

Exposure to low pH value can also result in similar effects. Below pH 4, redness and irritation of the eyes have been reported, the severity of which increases with decreasing pH. Below pH 2.5, damage to the epithelium is irreversible and extensive. In addition, because pH can affect the degree of corrosion of metals as well as disinfection efficiency, it may have an indirect effect on health.



3. Water produced by Enagic

(2) Strong Acidic Water (pH 2.5) is classified as **surface disinfectant** – used to disinfect all types of surfaces.

It is not notified with **National Pharmaceutical Regulatory Agency (NPRA)** as hand sanitizer.



3. Water produced by Enagic

What is the category for hand sanitizer product, is it classified as cosmetic product or generic product (Bukan Racun Berjadual/OTC; Over-The-Counter)?

- **Hand sanitizer can be categorized into 2 categories:**

(1) Cosmetic Product

(2) Generic Product (Bukan Racun Berjadual/OTC; Over-The-Counter)



3. Water produced by Enagic

(1) Cosmetic Product – for the purpose of maintaining hand hygiene (for general hand hygiene). The following are the regulatory requirements that must be complied with before importing, manufacturing, or marketing cosmetic products:

- (a) product has been notified with NPRA;
- (b) compliance with the requirements set out in the Guideline for Control of Cosmetic Products in Malaysia;
- (c) products are manufactured on premises that comply with the requirements of Good Manufacturing Practices (GMP) for cosmetic products or equivalent.



3. Water produced by Enagic

(2) Generic Product (Bukan Racun Berjadual/OTC; Over-The-Counter) – hand sanitizer/hand disinfectant/hand surgical scrub used in health facilities, to be used by health practitioners before and after performing treatment procedures.



3. Water produced by Enagic

What is a cosmetic product notification? Does it mean that the product has been approved by the MOH?

- Notification means **a declaration of compliance** by the company holding the notification with the rules, requirements and guidelines established for cosmetic products.
- With this, the company has taken responsibility to ensure that the product has been evaluated and ensured safe, quality and effective before it is marketed. Therefore, it is not a form of approval by the MOH. Notified products will be monitored from time to time and regulatory action will be imposed on products that do not comply with the prescribed rules.



3. Water produced by Enagic

What are the active ingredients that need to be in the hand sanitizer formulation that is classified as a cosmetic product?

- Hand sanitizer for notified cosmetics should contain **at least 60 % alcohol (ethanol or ethyl alcohol)**.
- For non-alcohol based sanitizers, sufficient documents and scientific evidence must be available to support the claims made on the label. Failure of the company to submit supporting documents within the stipulated period will result in rejection or cancellation of the notification. For canceled notifications, the product must be withdrawn from the market.



3. Water produced by Enagic

What are the allowable claims for hand sanitizers classified as cosmetic products?

- Hand sanitizers classified as cosmetic are for hygiene purposes. However, **antibacterial claims** are also allowed for cosmetic products as additional claims. However, claims such as disinfectant, antiseptic, antimicrobial, antiviral, antifungal, virucidical, reference to specific bacteria or disease-causing germs are not allowed for cosmetic products.

Can your water do this? (Its only water, FYI) good night! 🌙

Can your water do this?
A Healthier Hand Sanitizer
No More Chemicals for You or the Environment!
Start your Free Trial at beautywater.kb
Sanitizes and Disinfects

Kills in 30 Seconds

- MRSA
- VIRUSES
- BACTERIAS
- SALMONELLA
- ANTHRAX SPORES
- E-COLI

9.5 pH Kangen Water (hypochlorous acid)
Approved by the FDA and USDA for Food Handling and preparation

*For an even more powerful Hand Sanitizer add a few drops of Thieves Essential Oil and Drink Kangen 9.5pH water.

4 1



3. Water produced by Enagic

Are disinfectants used on tools or surfaces of objects/workspaces also classified as cosmetic products?

- No. Disinfectant products used to disinfect or disinfect medical devices are classified as medical device products. The product must obtain approval from the Medical Device Authority (MDA) before being allowed to be on the market.
- Disinfectant products used to disinfect all types of surfaces or workspaces are also classified as **general consumer products**.



4. Health Supplement

Kangen UKON Sigma Softgels is a **registered health supplement product** with National Pharmaceutical Regulatory Agency (NPRA).

Therefore, **all claims** in relation with the product **must be consistent** with Drug Registration Guidance Document (DRGD).



4. Health Supplement

Drug Registration Guidance Document (DRGD)

Section 4.1 – Definition

Section 4.1.1 – Health Supplement (HS)

A Health Supplement (HS) means any product that is used to **supplement a diet** and **to maintain, enhance** and **improve the health function** of human body. It is presented in small unit dosage forms (to be administered) such as capsules, tablets, powder, liquids and shall not include any sterile preparations (i.e. injectable, eyedrops).



4. Health Supplement

Drug Registration Guidance Document (DRGD)

Section 4.1 – Definition

Section 4.4.1 – Conditions

All claims made for HS shall:

- i) be consistent with the definition of HS;
- ii) enable consumers to make an informed choice regarding products;
- iii) not be misleading or false;
- iv) support the safe, beneficial and appropriate use of the product;



4. Health Supplement

Drug Registration Guidance Document (DRGD)

Section 4.1 – Definition

Section 4.4.1 – Conditions

All claims made for HS shall:

- v) maintain the level of scientific evidence proportional to the type of claims;
- vi) be for **health maintenance** and **promotion** purpose only;
- vii) **not be medicinal or therapeutic in nature**, such as implied for **treatment, cure or prevention of disease**.



4. Health Supplement

Drug Registration Guidance Document (DRGD)

Section 4.1 – Definition

Section 4.4.2 – Types and Evidence of Claims

i) A health supplement claim refers to the beneficial effects of consuming HS to promote good health and well-being (physical and mental) by providing nutrition, enhancing body structure/ function, relieving physiological discomfort and/or reducing the risk of health related conditions or diseases.



4. Health Supplement

Drug Registration Guidance Document (DRGD)

Section 4.1 – Definition

Section 4.4.2 – Types and Evidence of Claims

ii) Types of HS claims are:

- **General or Nutritional Claims (Table 1);**
- Functional Claims (medium) (Table 2);
- Disease Risk Reduction Claims (high) (Table 3);



4. Health Supplement

Drug Registration Guidance Document (DRGD)

Section 4.1 – Definition

Section 4.4.2 – Types and Evidence of Claims

ii) Types of HS claims are:

- **General or Nutritional Claims** (Table 1)

Table 1: General or Nutritional Claims

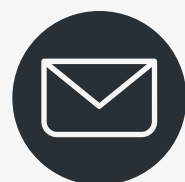
Level of claim	Definition	Examples/ Wording of claim	Criteria	Evidence to substantiate HS claims
General or Nutritional Claims	<ul style="list-style-type: none">▪ General Health Maintenance▪ Benefits derived from supplementation beyond normal dietary intake	<ul style="list-style-type: none">▪ Supports healthy growth and development▪ Nourishes the body▪ Relieves general tiredness, weakness▪ Helps to maintain good health▪ For energy and vitality▪ For strengthening the body	<ul style="list-style-type: none">▪ Is in line with established nutrition knowledge in reference texts▪ Is related to general well-being in line with scientific knowledge▪ Claim does not refer to the structure and/or function of the human body▪ In accordance to HS principles and practice in Malaysia	<p>1 or more of the following evidences:</p> <ul style="list-style-type: none">i) Standard reference e.g. reference textbooks, pharmacopoeia, monographsii) Recommendations on usage from reference regulatory authorities or reference organisations

Please refer to 4.4 Illustrative Substantiation Evidence List for the list of acceptable references, organisations and authorities.



Contact Us

Should you need further assistance,
please contact us at:



compliance@enagic-my.com



www.enagic-my.com



+03 2282 2332