



# Healy International Medical Device Certifications, Approvals and Clearance

Updated: December 15th, 2023



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# Healy International Medical Device Certifications, Approvals and Clearance

Healy is a smartphone-controlled wearable sold in two variants internationally. Healy is certified as a medical device in many countries, but also offers wellbeing and vitality applications in all markets in different variants.

## Healy is available in two variants

**Healy as a medical device**  
(in countries where Healy has medical device certification)



**Healy**  
REF 0006



**Healy as a non-medical device, Healy Wellness**  
(exclusively for wellbeing applications)



**Healy Wellness**  
REF 0009

REF = Hardware reference number

## Potential Healy Sales Scenarios for Various Countries:

Depending on the certification or approval per country, there are different constellations in which Healy variant is available in each country.



As a medical device with additional wellbeing applications.



As a medical device only with medical applications and also as a non-medical device only with applications for wellbeing.



As a non-medical device only with applications for wellbeing, although it is certified as a medical device.

*The reason being that Healy is not yet sold as a medical device in the respective market.*



Only as a non-medical device, exclusively with wellbeing applications.

Because the Healy hardware was developed as a medical device, it has also successfully passed electrical and electromagnetic safety testing to the highest standards.

On the following pages you will find a detailed overview of the countries where Healy is certified as a medical device, together with the indications for which Healy is certified in each country.

## HEALY INTERNATIONAL MEDICAL DEVICE CERTIFICATIONS, APPROVALS AND CLEARANCE



Here is a global overview of all countries where Healy has medical device certification\*.



\* Please note that Healy is a medical device in all countries listed on this map, but is not sold as a medical device in every country at this time. For Asia Pacific excluding India, Healy is sold as a Wellness device.





## European Union, Switzerland and Norway

As a medical device for medical applications only and also as a non-medical device for wellbeing applications only.

Healy with reference number REF 0006 is a medical device in all countries of the European Union with the following indications:

- Pain management (chronic pain, fibromyalgia, skeletal system pain, migraine).
- Mental illnesses such as depression, anxiety and associated sleep disturbances.

In Europe, Healy is available as a medical device with REF 0006, which contains only the programs according to the indications, and in addition as Healy Wellness, a non-medical device with REF 0009, containing only wellbeing programs.



Healy GmbH, as a medical device manufacturer, has conducted a PMCF (Post Market Clinical Follow-up) study with the Healy device under the European Medical Device Regulation with excellent results to confirm the following indications:

Chronic back pain, skeletal system pain, fibromyalgia, migraine, depression, anxiety and associated sleep disorders, with the following result:

## Post-market Clinical Follow-up Study on the Efficacy and Safety of the Healy Electrostimulation Device

### Assessment

- Health related Quality of Life (SF36)
- Pain Score Assessment (valid for chronic back pain and skeletal pain)
- Severity of Migraine Assessment (MIDAS; valid for indication migraine only)
- Mental Illness Assessment (PHQ-9, valid for indications fibromyalgia and depression only)
- Anxiety assessment (GAD-7, valid for indications fibromyalgia and depression only)
- Sleep quality (ISI, valid for indications fibromyalgia and depression only)

### Study procedure

1-2 per day indication specific Healy microcurrent applications

### Study groups / indications

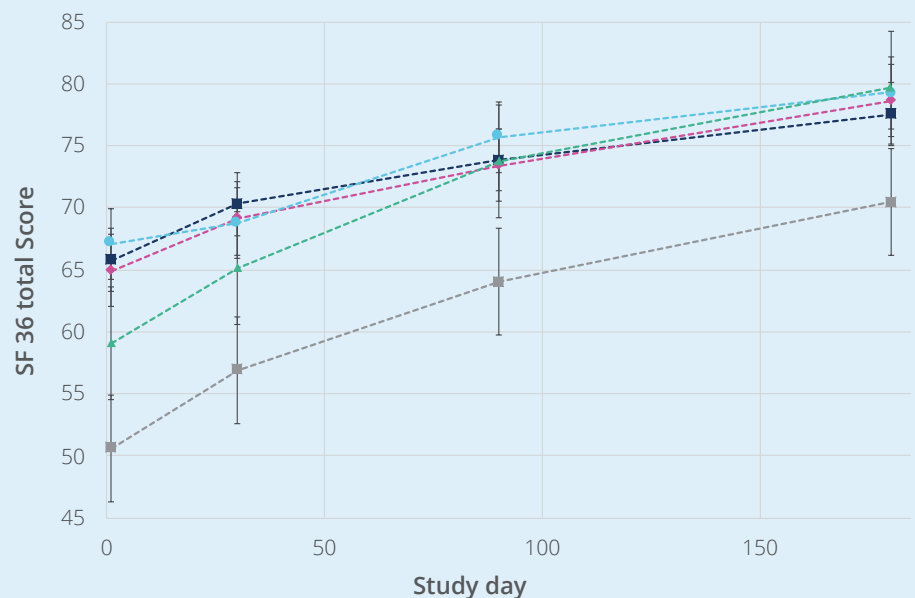
- Chronic back pain (N = 49)
- Skeletal system pain (N = 50)  
Fibromyalgia (N = 51)
- Migraine (N = 49)
- Depression, anxiety and associated sleep disorder (N = 50)

### Incentive

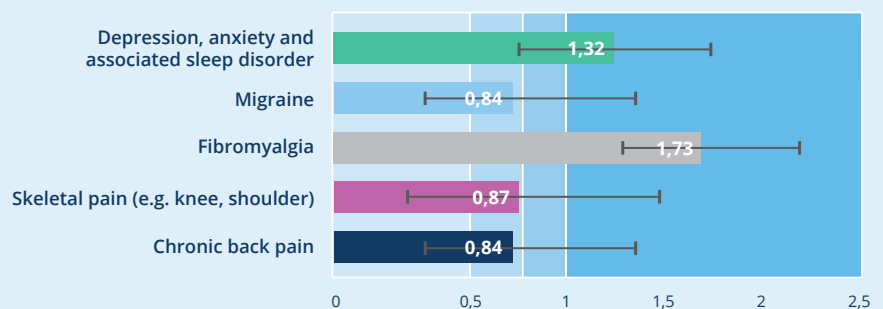
Healy Coil or Healy Watch

Observational study with 249 participants; Error bars = 95% confidence interval

Health related quality of life (SF 36 Total Score)



### Cohen's d RM\*



\*Effect size (Cohen's d for repeated measurements):

- d < 0.5 small effect
- d = 0.5 - 0.8 middle large effect
- d = 0.8 - 1.0 large effect
- d > 1.0 very large effect



Frequencies for Your Life

# EC-Declaration of Conformity

**Within the meaning of Council Directive 93/42 EEC  
of 14 June 1993 concerning medical device**

This is a class IIa medical device.

**Brand:** Healy

The product is designed and manufactured according to Directive 93/42/EEC under sole responsibility of:

**Company:** Healy GmbH  
Schloss Kränzlin  
Darritzer Strasse 6  
16818 Kränzlin - Germany

The technical documentation with risk analysis is completely available. This declaration is valid for at least 1 year after signing, at the latest until the expiry of the Annex-V-Certificate.

The product meets the essential requirements. The directions concerning the product are available. The conformity assessment procedure was carried out in accordance with Annex V and Annex VII to Directive 93/42/EEC.

The Notified Body is **MedCert**, Pilatuspool 2, Hamburg, Germany, with the identification number 0482.

The product complies with the applicable standards listed in the central list of standards of Healy GmbH.

Kränzlin, 07.01.2021



Place, date

CEO

**CE** 0482

Healy GmbH is certified as a medical device manufacturer and is the manufacturer of the Healy hardware according to the 93/42 EEC directive.



## Certificate

### The certification body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH**  
**Pilatuspool 2 – 20355 Hamburg – Germany**

herewith certifies that the company

**Healy GmbH**  
**Schloss Kränzlin, Darritzer Strasse 6**  
**16818 Kränzlin**  
**Germany**

has introduced, applies and maintains a quality management system in the area of:

#### **Manufacture, final inspection and distribution of**

- **Electro stimulation devices**
- **Devices for skin resistance measurement**

The conformity of this quality management system to the requirements of the below mentioned standard was verified by an audit:

### **EN ISO 13485:2016**

This certification is subject to surveillance by MEDCERT.

**Effective date:** 2021-10-06  
**Expiry date:** 2023-11-20

Report No.: 7426FS04F  
Procedure No.: QS – 7426  
Certificate No.: 7426GB445211006

Hamburg, 2021-10-06

  
\_\_\_\_\_  
MEDCERT Certification Body  
Marcus Harder

The certificate is only valid when provided entirely with all of its pages.  
To verify the validity of this certificate, contact [info@medcert.de](mailto:info@medcert.de).

MEDCERT is a DAKKS accredited management systems  
certification body

Form F10010017e EN / Rev. 9 / 2019.11.14



page 1 of 1





## EC Certificate of Conformity

### The Notified Body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH**  
**Pilatuspool 2 – 20355 Hamburg – Germany**

herewith certifies that the company:

**Healy GmbH**  
**Schloss Kränzlin, Darritzer Strasse 6**  
**16818 Kränzlin**  
**Germany**

has introduced, applies and maintains a quality assurance system for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

### Annex V

This certification is subject to surveillance by MEDCERT.

**Effective date:** 2020-11-03

**Expiry date:** 2023-12-12

Report No.: 7426PS03  
Process No.: QS – 7426  
Certificate No.: 7426GB414201103A

Hamburg, 2020-11-03

MEDCERT Certification Body  
(Markus Bianchi)

The certificate is only valid when provided entirely with all of its pages.  
To verify the validity of this certificate, contact [info@medcert.de](mailto:info@medcert.de).

MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)  
ZLG-BS-237.10.15

page 1 of 2



**Appendix of EC Certificate of Conformity**

Process No.: QS – 7426

Certificate No.: 7426GB414201103A

**List of products / product categories included in the scope of certificate**

**Electro stimulation devices**

– End of list –

This appendix is integral part of the above-referenced certificate.  
The certificate is only valid when provided entirely with all of its pages.  
To verify the validity of this certificate, contact [info@medcert.de](mailto:info@medcert.de).

MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)  
ZLG-BS-237.10.15

page 2 of 2



## United States of America

As a medical device with additional applications for wellbeing.

Healy with REF 0006 has been cleared by the FDA as a medical device in the United States of America for the following indications:

- Temporary relief of pain associated with sore muscles in the shoulder, waist, back, arms, and legs caused by exercise or normal household activities; symptomatic relief and treatment of chronic, persistent pain; and relief of pain associated with arthritis.

In the United States of America, Healy is available with REF 0006 as a medical device and also contains wellbeing programs.





Frequencies for Life

# Confirmation of Legal Status

This confirms that

## HEALY

has been FDA cleared for over the counter sale

**510(k) Number: K191075**

With Indications for Use:

The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, arms and legs due to strain from exercise or normal household work activities and for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

A handwritten signature in black ink, reading "Douglas Herrington".

Douglas Herrington  
Principal Consultant, Herrington Consulting LLC

November 22, 2019



## Canada

As a medical device with additional wellbeing applications.

Healy with REF 0006 has a medical device licence in Canada for the following indications:

- Temporary relief of pain associated with sore muscles in the shoulder, waist, back, neck, upper and lower extremities due to strain from exercise or normal household work activities.
- Symptomatic relief and management of chronic, intractable and relief of pain associated with arthritis, neuralgia, myalgia and fibromyalgia.

In Canada, Healy is available as a medical device with REF 0006 and also includes wellbeing programs.





Santé Health  
Canada Canada

LN/NH: 106300

Medical Devices Directorate  
Direction des instruments médicaux

## Medical Device Licence

## Homologation d'un instrument médical

**Licence Number:** 106300

**No d'homologation:**

**First Issue Date:** 2021/06/17

**Première date de délivrance:**

### **Device Class/Classe de l'instrument: 2**

This Licence is issued in accordance with the  
Medical Devices Regulations, Section 36,  
for the following medical device:

La présente homologation est délivrée en vertu  
de l'article 36 du Règlement sur les instruments  
médicaux pour l'instrument médical suivant:

### **Licence Name/Nom de l'homologation:**

HEALY

### **Licence Type/Type d'homologation:**

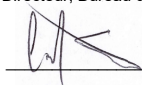
Single Device / Instrument à article unique

### **Manufacturer Name & Address/Nom du fabricant & adresse**

#### HEALY GMBH

SCHLOSS KRANZLIN, DARRITZER STR. 6  
KRANZLIN, BRANDENBURG  
GERMANY  
16818

Colin Foster, Director, Bureau of Medical Device Licensing Services  
Directeur, Bureau des services d'homologation des instruments médicaux



**Application Number:** 331549  
**Numéro de la demande:**

**Manufacturer ID:** 164914  
**Identificateur du fabricant:**



Santé Health  
Canada Canada

LN/NH: 106300

Medical Devices Directorate  
Direction des instruments médicaux

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**Components/Parts/Accessories/Devices for this Licence**  
**Les composantes, parties, accessoires et instruments médicaux pour cette homologation**

HEALY

**Device ID/No de l'instrument: 1031793**  
**Device Identifier / Identificateur de l'instrument**  
**(Model/Catalog Detail/No de modèle/Catalogue):**

REF 0006

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Application Number:  
Numéro de la demande: 331549

Page 2

Manufacturer ID:  
Identificateur du fabricant:

164914

## India

As a medical device with additional wellbeing applications.

Healy with REF 0006 is sold in India as a medical device with the following indications:

- Pain management (chronic pain, fibromyalgia, skeletal system pain, migraine).
- Mental illnesses such as depression, anxiety and associated sleep disturbances.

In India, Healy is available as a medical device with REF 0006 and also includes programs for wellbeing.





**No.29/Misc./03/2019-DC (194)**  
**Government of India**  
**Directorate General of Health Services**  
**Central Drugs Standard Control Organisation**  
**(Medical Device Division)**

FDA Bhawan, Kotla Road,  
New Delhi-110002.

Dated: **24 AUG 2020**

To,  
**M/s. Healy World Trading India Pvt. Ltd.,**  
**A/3, S/F Front Side Kundan Mansion,**  
**Asaf Ali Road, Turkman Gate,**  
**New Delhi-110002.**

**Sub: - Application for grant of NOC for the product viz., Healy - Regd.**

Sir,

Please refer to your application no. Nil dated 09.06.2020 received by this office vide Diary no.4521 dated 22.06.2020 regarding the above mentioned subject.

The case has been examined in the light of documents submitted by you. In this connection, it is stated that the product viz., **Healy** used in pain management (chronic pain, fibromyalgia, skeletal system pain, migraine) and in case of mental illnesses such as depression, anxiety and associated disturbance) is not currently under licensing as per Drugs and Cosmetics Act and Medical Device Rules, 2017 thereunder. However, as per the S.O. 648(E) dated 11.02.2020 the proposed product falls under the definition of Medical Device.

In view of above, you are requested to comply with the voluntary registration requirements for the product in portal established by CSDCO as per G.S.R. 102 (E) dated 11.02.2020.

Yours faithfully,



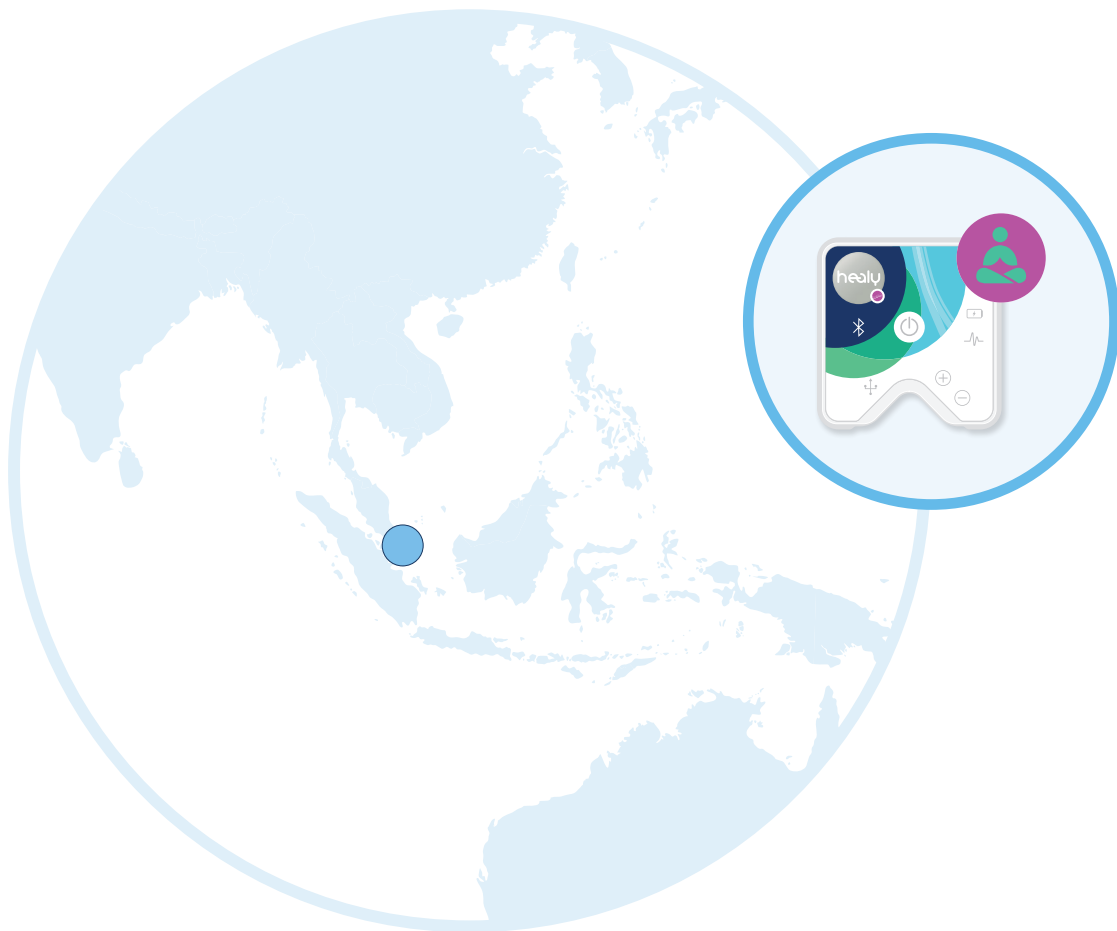
**(Dr. Ravi Kant Sharma)**  
**Deputy Drugs Controller (I)**

## Singapore

Healy with REF 0006 is registered as a medical device in Singapore for the following indications:

- Pain management (chronic pain, fibromyalgia, skeletal system pain).

In Singapore, Healy Wellness with REF 0009 is currently only available as a non-medical device, containing programs for wellbeing only.





1/20/2021

Public Enquiry - Singapore Medical Device Register (SMDR)

**PUBLIC ENQUIRY - SINGAPORE MEDICAL DEVICE REGISTER (SMDR)**

**Device Info**

**Device Name:** **TimeWaver Healy System** [TimeWaver Production GmbH]  
**Description:** Healy is a microcurrent stimulation device that supports the treatment of symptoms of diseases, using currents in the microampere range with different frequencies. It can be applied to different areas of the body. The intended use of the Healy includes the following fields of application: • in pain management (chronic pain, fibromyalgia, skeletal system pain).  
**Medical Specialty Area:** General Hospital  
**Medical Device Class:** Class B medical device  
**Device Registration No:** DE0505366  
**Registration Date:** 20/01/2021  
**Change Notification Approval Date:** Not Applicable  
**Device System Info:** [System or Procedure Pack], Healy hardware device Press button adhesive electrodes round Ø 32mm Connection cable for electrodes 96 cm – press button on 2mm Bracelet electrode (black, carbon) Ear electrodes (pair) Felts Charging cable USB 0.15 m

**Product Owner**

1. [TimeWaver Production GmbH](#) [TimeWaver Production GmbH] Schloss Kränzlin, Darritzer Strasse 6, 16818 Kränzlin, GERMA...

**Registrant**

1. [KROMAX SOUTH ASIA PTE. LTD.](#) 26 SIN MING LANE, MIDVIEW CITY, #07-118, SINGAPORE 573971

**Models**

No.	Model Name	Identifier	Place of Manufacture
1	Connection cable 96cm - press button on 2mm	REF 108-4062	CHINA, ITALY
2	Bracelet electrode	REF 108-4061	CHINA, ITALY
3	Ear clip electrodes	REF 108-4004	CHINA
4	Felts	REF 108-4096	CHINA
5	Healy	REF 0006	GERMANY
6	Press button adhesive electrodes round Ø 32 mm	REF 108-4063	ITALY

[Close](#)

**Note:** All device listings on the Singapore Medical Device Register (SMDR) are active. Class A medical devices are not registered in the SMDR. To retrieve Class A medical devices, please visit [Class A Medical Device Database](#).



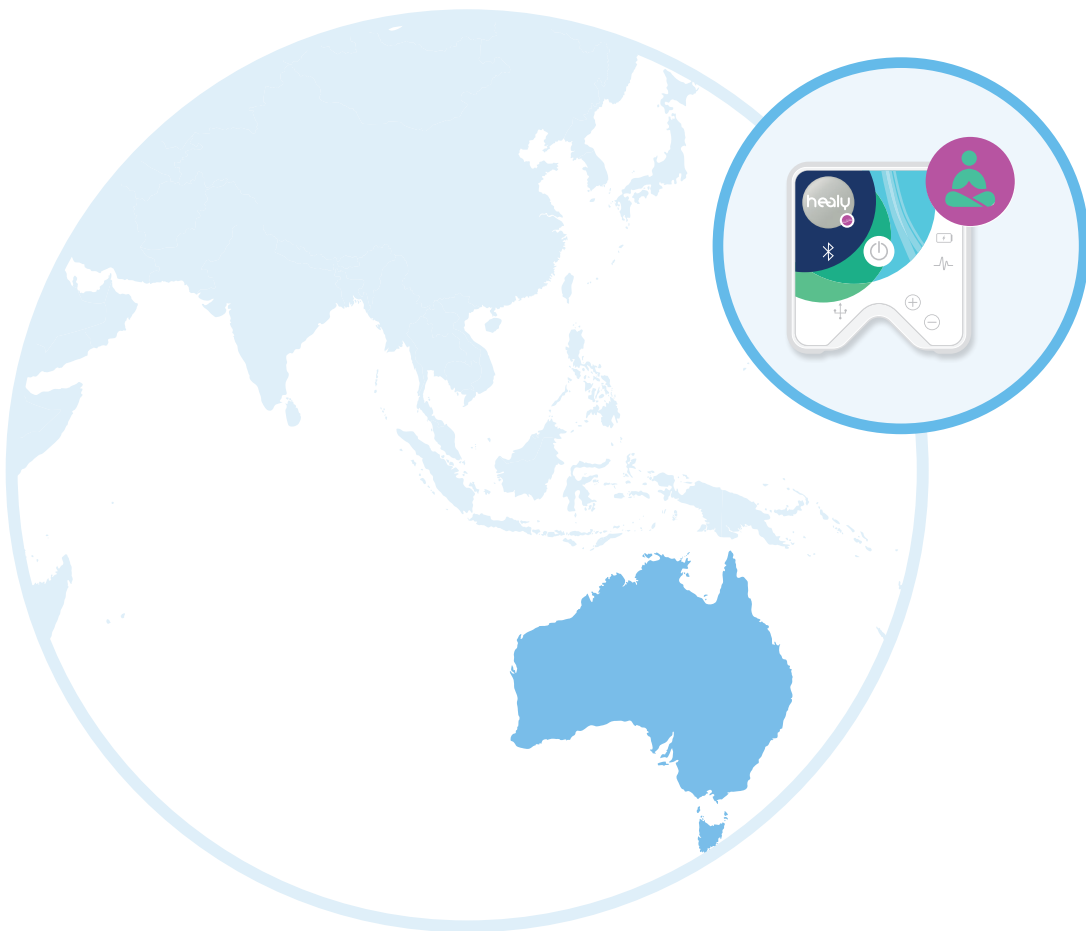
Health Sciences Authority

## Australia

Healy with REF 0006 has medical device approval in Australia for the following indications:

- Pain management (chronic pain, fibromyalgia, skeletal system pain, migraine).

In Australia, Healy Wellness with REF 0009 is currently only available as a non-medical device, offering only wellbeing programs.







Australian Government

Department of Health and Aged Care  
Therapeutic Goods Administration

## Australian Register of Therapeutic Goods Certificate

Issued to

**Healy World Australia Pty Ltd**

for approval to supply

**Healy World Australia Pty Ltd - Analgesic TENS system**

<b>ARTG Identifier</b>	336551
<b>ARTG Start Date</b>	18/05/2020
<b>Product Category</b>	Medical Device Included Class IIa
<b>GMDN</b>	35372
<b>GMDN Term</b>	Analgesic TENS system
<b>Intended Purpose</b>	This is a transdermal micro electrical stimulating device that is intended to be used on the surface of the human skin to transmit micro electrical current for pain syndromes. The indications are pain management for chronic pain, fibromyalgia, skeletal system pain and migraine.

Manufacturer Details	Address	Certificate number(s)
Healy GmbH	Schloss Kranzlin Darritzer Strasse 6 , Kranzlin , 16818 Germany	DV-2021-MC-19221-1

### ARTG Standard Conditions

The above Medical Device Included Class IIa has been entered on the Register subject to the following conditions:

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

### Products Covered by This Entry

#### 1. Analgesic TENS system

### Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration  
PO Box 100, Woden ACT 2606 Australia  
Phone: 1800 020 653  
Email: [info@tga.gov.au](mailto:info@tga.gov.au)

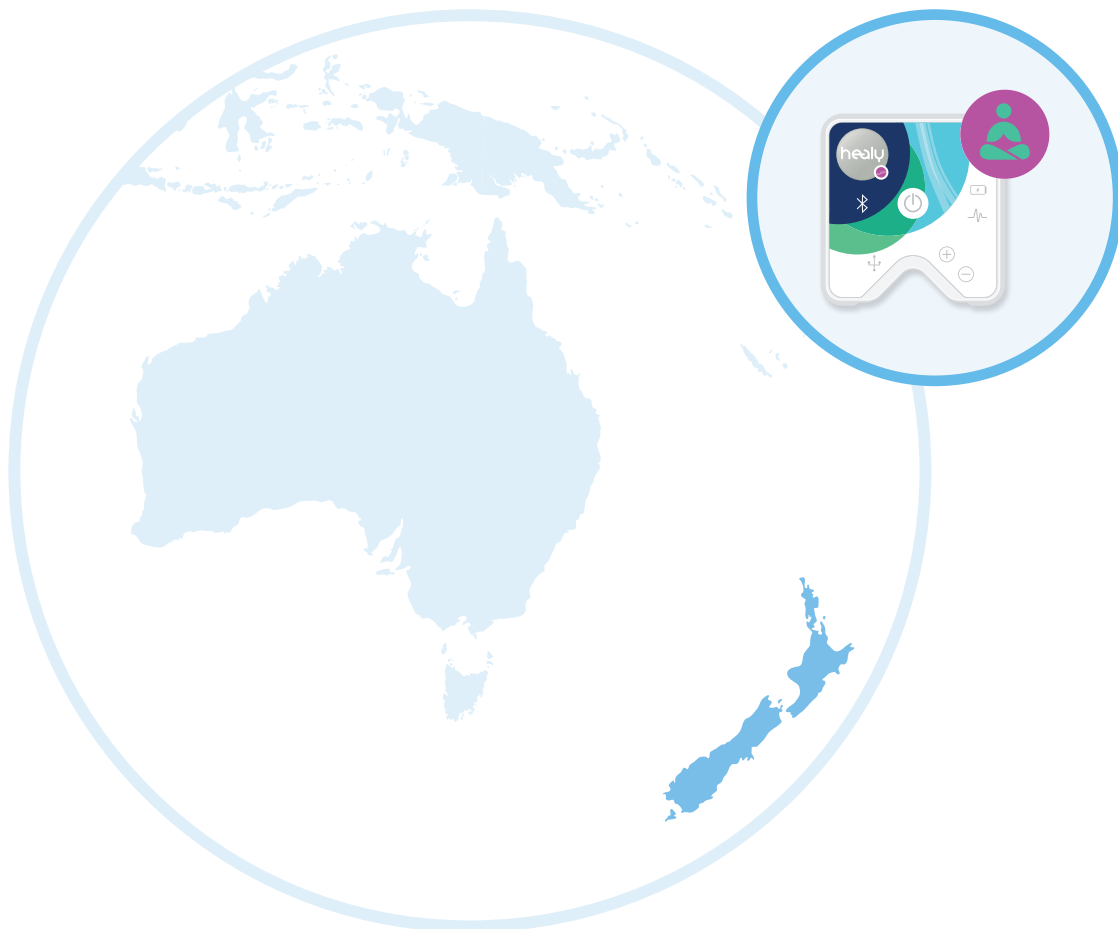
ARTG Identifier: 336551  
ARTG Start Date: 18/05/2020

## New Zealand

Healy with REF 0006 has medical device approval in New Zealand for the following indications:

- Pain management (chronic pain, fibromyalgia, skeletal system pain, migraine).

In New Zealand, Healy Wellness with REF 0009 is currently only available as a non-medical device, offering only wellbeing programs.



20/08/2021

Medical Device Detail - Printer Friendly Form



## Medical Device Details

Sponsor: Healy World New Zealand Limited  
Level 11  
41 Shortland Street  
Auckland  
New Zealand

WAND Reference: 210820-WAND-6XFL2G

Sponsors Own Reference: Healy

GMDN: Analgesic TENS system [35372]

Class: IIa

Intended Purpose: Healy is a transdermal micro electrical stimulating device that is intended to be used on the surface of the human skin to transmit micro electrical current for pain syndromes. It can be applied to different areas of the body. The indications are pain management for chronic pain, fibromyalgia, skeletal system pain and migraine.

Manufacturer: Healy GmbH Darritzer Strasse 6  
Kranzlin  
Germany

ARTG ID: 336551

- › The device is supplied unsterilised.
- › The device is not intended to be invasive.
- › The device is not intended for single use.
- › The device is an active device.
- › The device does not contain material or ingredients of microbial origin.
- › The device does not contain material or ingredients of recombinant origin.
- › The device does not contain material or ingredients manufactured or formulated using a genetically modified organism.
- › The device does not contain material or ingredients of human origin.
- › The device does not contain human blood or its components.
- › The device consists of: Single product
- › The device does not contain material or ingredients of animal origin.
- › The device is not medicated.
- › The device is not formulated.
- › The product does not contain a medicine that has consent for marketing in New Zealand.
- › The product does not contain a medical device which incorporates a medicine as an integral part and that has an action ancillary to the device.

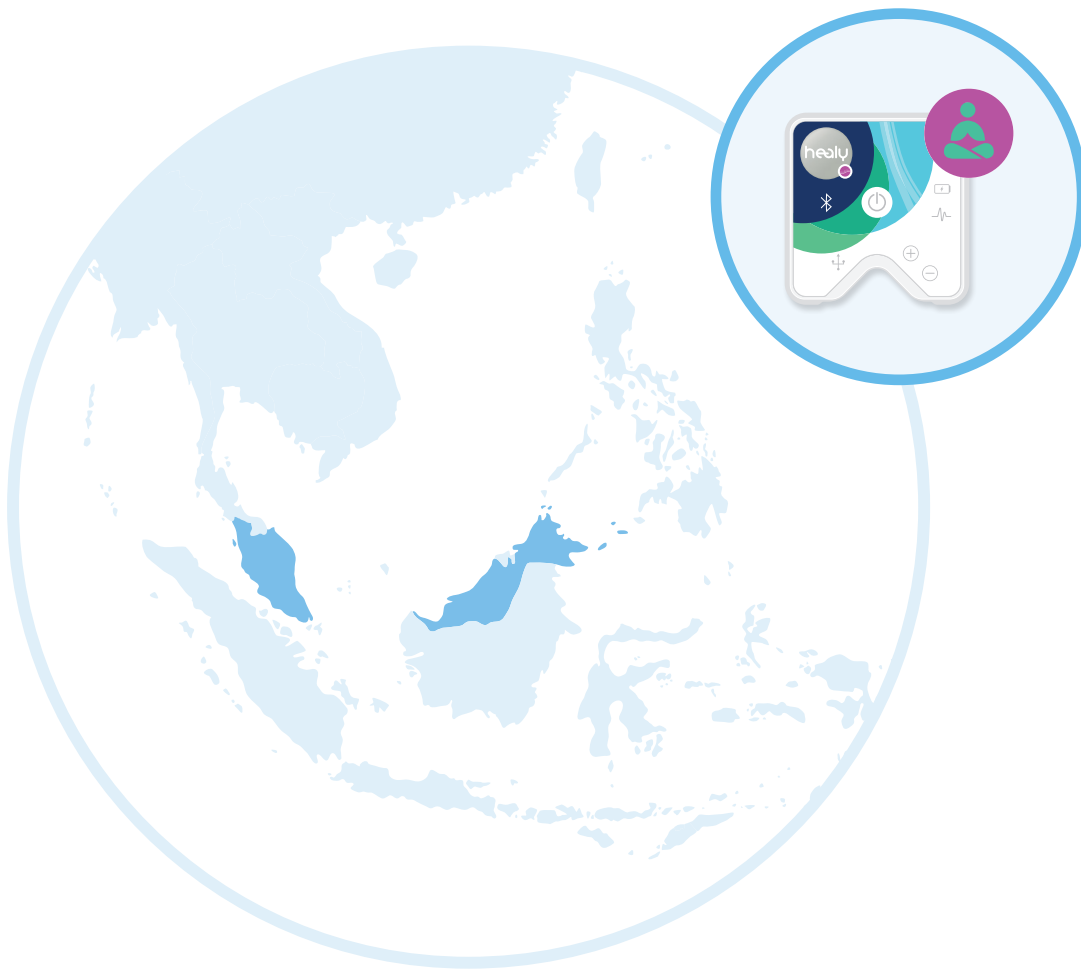
Status: Active

## Malaysia

Healy with REF 0006 is registered as a medical device in Malaysia for the following indications:

- Pain management (chronic pain, fibromyalgia, skeletal system pain, migraine).
- Mental illnesses such as depression, anxiety and associated sleep disturbances.

In Malaysia, Healy Wellness with REF 0009 is currently only available as a non-medical product, offering only wellbeing programs.



No. Siri: **036247**  
Serial No.:

ASAL  
ORIGINAL

PIHAK BERKUASA  
PERANTI PERUBATAN



MEDICAL DEVICE  
AUTHORITY

**PIHAK BERKUASA PERANTI PERUBATAN**  
MEDICAL DEVICE AUTHORITY  
**AKTA PERANTI PERUBATAN 2012 (AKTA 737)**  
MEDICAL DEVICE ACT 2012 (ACT 737)  
**SIJIL PENDAFTARAN PERANTI PERUBATAN**  
MEDICAL DEVICE REGISTRATION CERTIFICATE  
**Seksyen 5(1) Akta 737**  
Section 5(1) of Act 737

No. Pendaftaran: **GB1111720-46115**  
Registration No.:

Tarikh Sah Pendaftaran: **12/08/2020 - 11/08/2025**  
Registration Validity Date:

Sijil ini adalah dengan ini diberi kepada:  
*This certificate is hereby issued to:*

**ANDAMAN MEDICAL BRIDGE SDN. BHD.**

yang beralamat di:  
*which is located at:*

**UNIT 3.3A, 3RD FLOOR WISMA LEADER, NO.8  
JALAN LARUT, 10050 PENANG,  
10050  
PULAU PINANG PULAU PINANG PULAU  
MUTIARA**

bagi mengesahkan peranti perubatan seperti yang dinyatakan dalam Lampiran 1 adalah berdaftar di bawah Seksyen 5(1) Akta 737.  
*to confirm that the medical device as detailed out in Attachment 1 is registered under Section 5(1) of Act 737.*

Pendaftaran ini diberikan tertakluk kepada peruntukan-peruntukan di bawah Akta 737 dan peraturan-peraturan yang dibuat dibawahnya serta syarat-syarat seperti di Lampiran 2.  
*This registration is granted subject to the provisions under Act 737 and its subsidiary legislations and the conditions as in Attachment 2.*



**AHMAD SHARIFF BIN HAMBALI**  
KETUA EKSEKUTIF  
CHIEF EXECUTIVE  
PIHAK BERKUASA PERANTI PERUBATAN  
MEDICAL DEVICE AUTHORITY

LAMPIRAN 1  
Attachment 1



No. Pendaftaran: **GB1111720-46115**

Registration No.:

Butir-butir peranti perubatan yang didaftarkan

Particulars of the registered medical device

Nama Peranti Perubatan **HEALY**

Medical Device Name

Kelas

**CLASS B**

Jenama

**HEALY (0006)**

Class

Brand

Kelompok

**SYSTEM**

Group

Nama dan alamat

pembuat:

Name and address of

manufacturer

**HEALY GMBH**

**SCHLOSS KRÄNZLIN, DARRITZER STRASSE 6 16818 KRÄNZLIN, GERMANY**

**16818**

**GERMANY**

**APPENDIX**

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1	Healy	0006	A portable device, internally powered and controlled via Bluetooth by a software application that is installed on a Smartphone. It has one stimulation output. The stimulation output can be varied between -10 V and +10 V, 0 to 1 MHz, 0 - 4 mA.
2	Healy APP	Healy APP	"Healy APP" is required for configuring and controlling the hardware. It allows sending treatment programs to the device. With the App you can start and stop the treatment. The "Healy APP" connects to your Healy hardware using Bluetooth. The "Healy APP" can connect only to one device at a time.
3	Ear electrodes (pair)	108-4004	Ear electrodes
4	Connection cable 96cm - press button on 2mm	108-4062	Connection cable for electrodes 96cm
5	Direct plug-in AC/DC adaptor	JHD-AP006E-050100BB-A	Adaptor

LAMPIRAN 1  
Attachment 1



NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
6	Press button adhesive electrodes round Ø32 mm	108-4063	Self adhesive surface electrodes with button connector and 32mm diameter
7	Felts	108-4096	Felts that are placed on the ear electrodes
8	Charging cable USB 0.15 m	108-4068	Charging cable for the Healy device
9	Bracelet electrode (black, carbon)	108-4061	Electrodes for the wrists
"End Of Product List"			

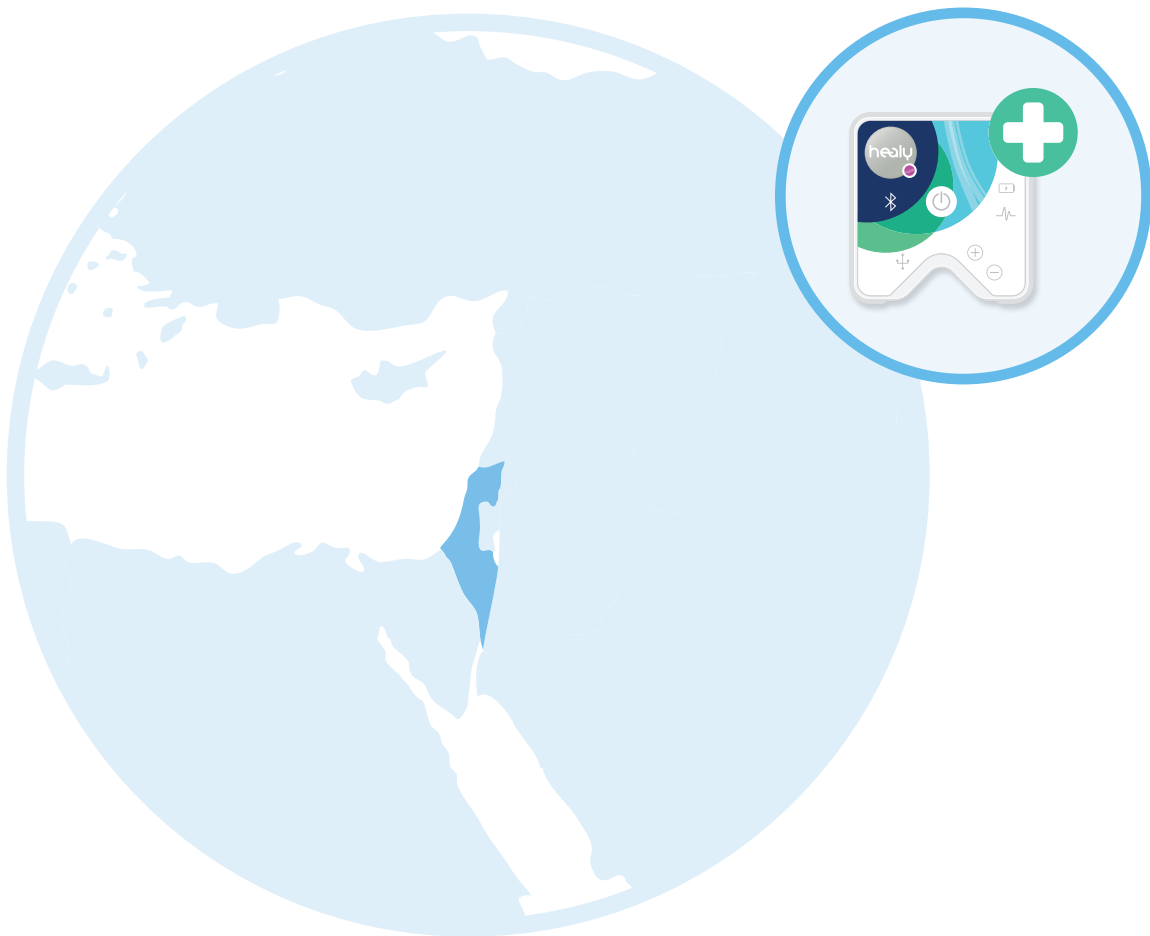


## Israel

Healy with REF 0006 has medical device certification in Israel for the following indications:

- Pain management (chronic pain, fibromyalgia, skeletal system pain, migraine).
- Mental illnesses such as depression, anxiety and associated sleep disturbances.

Healy is not yet officially being sold in Israel.



Ministry of Health  
Medical Technology, Information and Research Division  
Medical Devices Department



משרד הבריאות  
חטיבת טכנולוגיות רפואיות, מידע ומחקר  
אגף ציוד רפואי

## אישור הגשת בקשה לחידוש רישום

תאריך הגשה  
01/08/2022

מספר רישום  
26760015

מספר פניה  
54415

הריני לאשר קבלת בקשה לרישום מחברת דור שירותים פרמצבטיים בע"מ

עבור הציוד הרפואי (אמ"ר) :

**Healy**

הילי

Healy GmbH ; Schloss Kranzlin, Darritzer Strasse 6, 16818 Kranzlin ; GERMANY

שם יצרן וכתובתו -

הערות:

חתימה

01/08/2022  
תאריך הדפסה

Ministry of Health  
Medical Technology, Information and Research Division  
Medical Devices Department



משרד הבריאות  
חטיבת טכנולוגיות רפואיות, מידע ומחקר  
אגף ציוד רפואי

## אישור רישום בפנקס הציוד הרפואי

ניתן בזאת אישור, כי בהתאם לבקשת רישום מס : 26760015  
הציוד הרפואי (אביזרים / מכשירים רפואיים (אמ"ר)) הבא :

Healy	הילי	שם הציוד הרפואי
1. Healy		קבוצות
The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, arms and legs due to strain from exercise or normal household work activities and for the symptomatic relief and management		יעוד הציוד הרפואי
The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, arms and legs due to strain from exercise or normal household work activities and for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis		התויה
דור שירותים פרמצבטיים בע"מ ; התע"ש 20, כפר סבא ; ישראל		שם בעל הרישום וכתובתו
Healy GmbH ; Schloss Kranzlin, Darritzer Strasse 6, 16818 Kranzlin ; GERMANY		שם היצרן וכתובתו
VTQ Videotronik GmbH, - Gruene Strage 2, 06268 Querfurt, Germany - GERMANY .1		שם אתר היצור וכתובתו
<b>התניות</b>		
<p>הנחיות</p> <ul style="list-style-type: none"> <li>- לפי הוראות היצרן שאושרו ע"י גוף המאשר: FDA, medcert'.</li> <li>- אישור בהתאם לאישור FDA/CE ומערכת איכות בתוקף.</li> <li>- מאושר לשימוש בהתאם להוראות היצרן, כפי שאושרו ע"י הגופים המאשרים.</li> <li>- יש לעמוד בהנחיות לסימון ציוד רפואי המיועד למשתמש הביתי.</li> <li>- בעל הרישום (או היבואן) לא יחזיק מלאים אלא יבצע יבוא בשיטת "גב אל גב" (back to back) ישירות אל מוסדות הרפואה.</li> </ul>		

נרשם בפנקס הציוד הרפואי (האמ"ר) במשרד הבריאות.  
תוקף האישור לשיווק הציוד הרפואי (האמ"ר) הינו ליעודים ולהתוויות  
המתוארים לעיל בלבד.  
האישור בתוקף עד : 30/11/2022



חתימה

31/01/2021

תאריך חתימת האישור

ד"ר נדב שפר  
מנהל אגף ציוד רפואי

שם ותפקיד המאשר

## Indonesia

Healy with REF 0006 has medical device certification in Indonesia for the following indications:

- Pain management (chronic pain, fibromyalgia, skeletal system pain, migraine).
- Mental illnesses such as depression, anxiety and associated sleep disturbances.

Healy is not yet officially being sold in Indonesia.





**KEMENTERIAN KESEHATAN REPUBLIK INDONESIA**  
**DIREKTORAT JENDERAL KEFARMASIAN DAN ALAT KESEHATAN**  
Jalan H.R. Rasuna Said Blok X-5 Kavling 4 - 9 Jakarta 12950  
Telepon : (021) 5201590 Pesawat 2029, 8011  
Faksimile : (021) 52964838 Kotak Pos : 203



Berdasarkan Peraturan Menteri Kesehatan R.I Nomor 62 Tahun 2017 Tentang Izin Edar Alat Kesehatan, Alat Kesehatan Diagnostik In Vitro Dan Perbekalan Kesehatan Rumah Tangga dengan ini diberikan persetujuan untuk diedarkan dengan :

NOMOR IZIN EDAR

**ALAT KESEHATAN**

**KEMENKES RI AKL 21003120923**

Nama Dagang / Merek : **HEALY**  
Kelompok / Kelas Resiko : Elektromedik Non Radiasi / C  
Kategori Produk : Peralatan Neurologi  
Sub Kategori : Peralatan Neurologi Terapetik  
Jenis Produk : Transcutaneous electrical nerve stimulator for pain relief.  
Tipe / Ukuran : Ref. 0006  
Kemasan : Unit  
Nama Produsen / Pabrikan : HEALY GMBH, Germany  
Nama Pendaftar : PT. ANDAMAN MEDICAL INDONESIA, DKI Jakarta  
Atas dasar lisensi dari : -

**Ketentuan**

1. Persetujuan izin edar berlaku sampai dengan 10 Maret 2025.
2. Wajib menyampaikan laporan berkala dan laporan jika ada kejadian yang tidak diinginkan akibat penggunaan Alat Kesehatan tersebut di atas sesuai ketentuan berlaku.
3. Apabila dikemudian hari ada pihak lain yang berhak atas merek dan/atau keagenan produk tersebut, pendaftar bersedia mengembalikan izin edar.
4. Penandaan dan informasi produk yang terlampir merupakan bagian yang tidak terpisahkan dari persetujuan izin edar ini.
5. Apabila di kemudian hari terdapat kekeliruan, maka persetujuan izin edar ini akan ditinjau kembali.

Jakarta, 18 Februari 2021



**Catatan:**

- UU ITE No 11 Tahun 2007 Pasal 5 ayat 1
- Informasi Elektronik dan/atau Dokumen Elektronik dan/atau hasil cetaknya merupakan alat bukti hukum yang sah.
- Dokumen ini telah ditandatangani secara elektronik menggunakan sertifikat elektronik yang diterbitkan BSR.E.



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[www.healy.world](http://www.healy.world)