Frequencies for Your Life

Healy International Medical Device Certifications, Approvals and Clearance

Updated: January 1, 2023

Vers. 1.0 | 2023-03-07

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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.

Frequencies for 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 INTERNATIONAL MEDICAL DEVICE CERTIFICATIONS, APPROVALS AND CLEARANCE

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

MEDCERT®
Certification. Medical Only.

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.

MEDCERT is a DAkkS accredited management systems certification body

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-19630-04-00

Form F10010017e EN / Rev. 9 / 2019.11.14

page 1 of 1

MEDCERT®
Certification. Medical Only.

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.

MEDCERT Identification Number: 0482

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

Form F10010005e EN / Rev. 11 / 2019.11.14

MED CERT®
Certification. Medical Only.

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.

MEDCERT Identification Number: 0482

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

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.

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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.

November 22, 2019

Douglas Herrington
Principal Consultant, Herrington Consulting LLC

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 Canada Health 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:
Numéro de la demande: 331549

Manufacturer ID:
Identificateur du fabricant: 164914

Santé Canada Health Canada

LN/NH: 106300

Medical Devices Directorate
Direction des instruments médicaux

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

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,

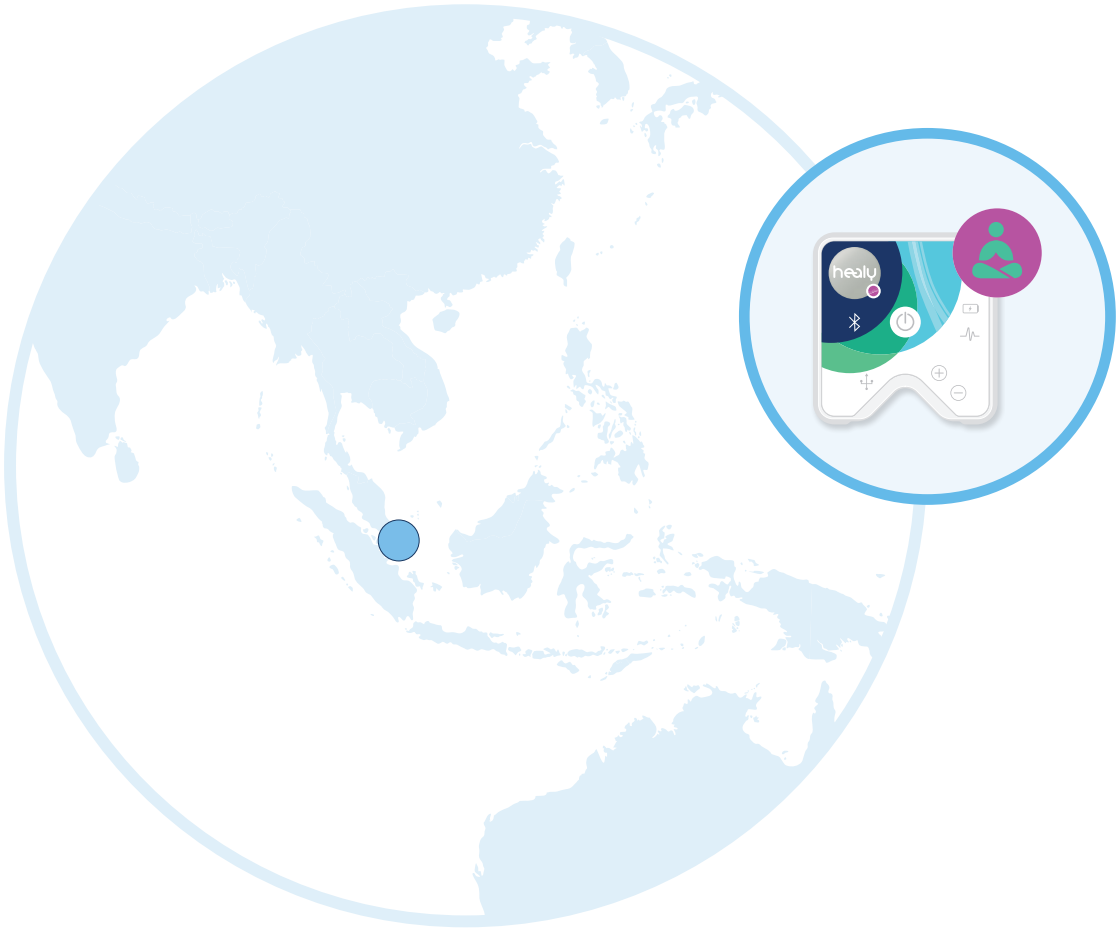
(Dr. Ravi Kant Sharma)
Deputy Drugs Controller (I)

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.



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.

SINGAPORE QUALITY CLASS STAR
PEOPLE · SERVICE

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

Public Summary

Summary for ARTG Entry:	336551	Healy World Australia Pty Ltd - Analgesic TENS system

ARTG entry for	Medical Device Included Class IIa
Sponsor	Healy World Australia Pty Ltd
Postal Address	201 Elizabeth Street, Sydney, NSW, 2000 Australia
ARTG Start Date	18/05/2020
Product Category	Medical Device Class IIa
Status	Active
Approval Area	Medical Devices

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.

Manufacturers

Name	Address
Healy GmbH	Schloss Kranzlin Darritzer Strasse 6 , Kranzlin, 16818 Germany

Products

1 . Analgesic TENS system

Product Type	Single Device Product	**Effective Date**	18/05/2020
GMDN	35372 Analgesic TENS system		
Intended Purpose	This is a transdermal micro electrical stimulating device that is intended to be used on the surface of the human skin to transmit micro electoral current for pain syndromes. The indications are pain management for chronic pain, fibromyalgia, skeletal system pain and migraine.		

Specific Conditions

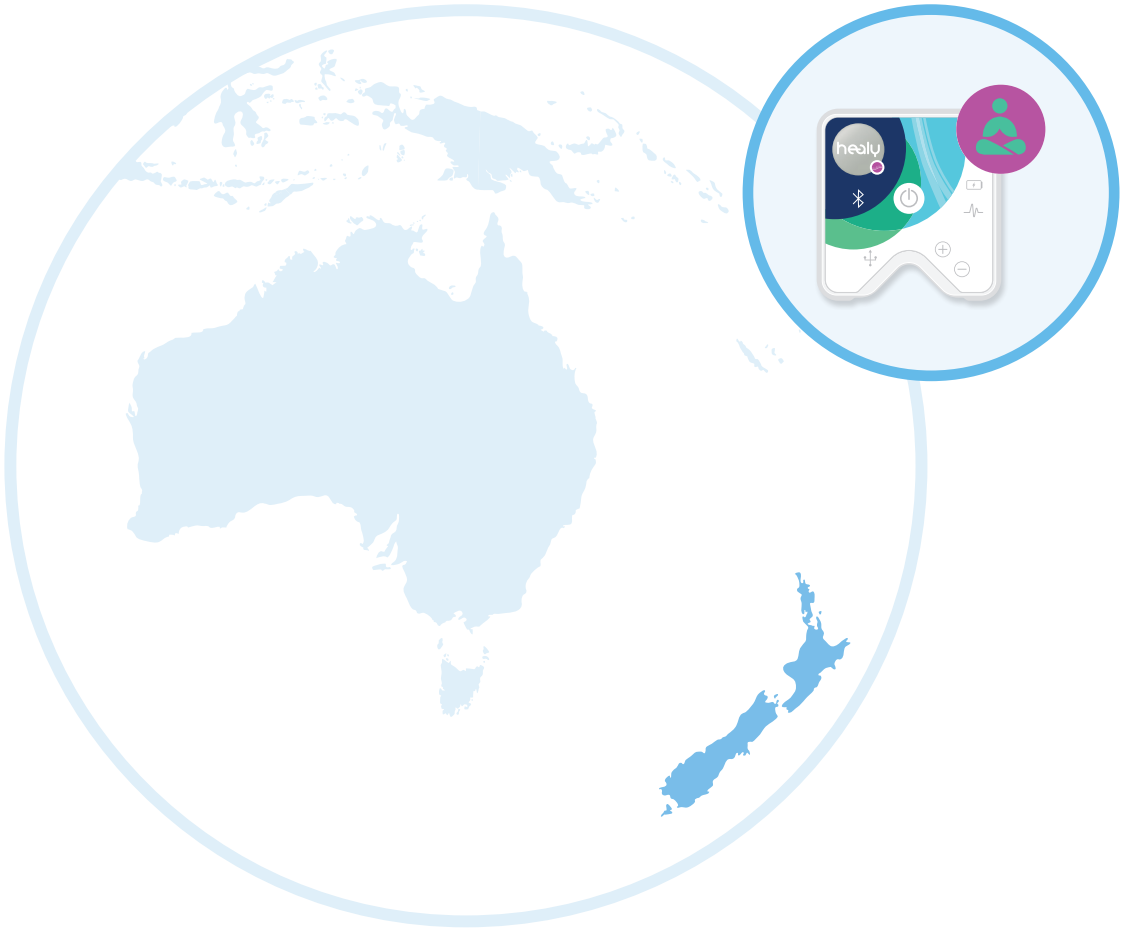
No Specific Conditions included on Record

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.



Medical Device Details

Sponsor:	Healy World New Zealand Limited Level 11 41 Shortland Stret Auckland New Zealand
WAND Reference:	210820-WAND-6XFL2G
Sponsors Own Reference:	Healy
GMDN:	Analgesic TENS system [35372]
Class:	IIa
Intended Purpose:	Healy is a is a transdermal micro electrical stimulating device that is intended to be used on the surface of the human skin to transmit micro electoral 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.

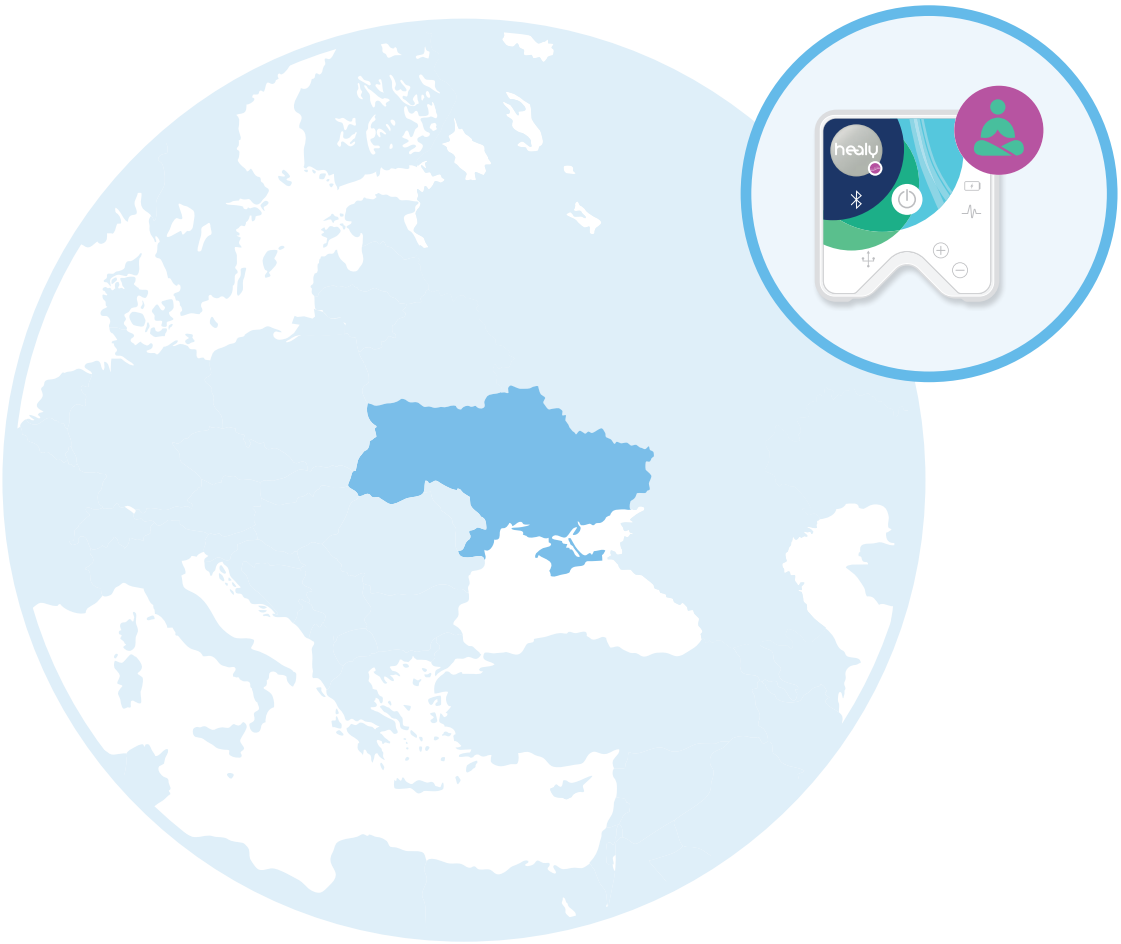
Status: Active

Ukraine

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

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

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



Декларація про відповідність № UK_2505

(Declaration of conformity # UK_2505)

Загальна назва виробу: *Common name of medical device:*	**Пристрої для електростимуляції** *Electro stimulation devices*
Перелік виробів: *List of products:*	**HEALY™** *HEALY™*
Виробник: *Manufacturer:*	**Хілі ГмбХ** Шлос Кранцлін, Даррітцер штрассе 6, 16818 Кранцлін, Німеччина ***Healy GmbH*** *Schloss Kränzlin, Darritzer Strasse 6, 16818 Kränzlin, Germany*
Уповноважений представник в Україні: *Authorized representative in Ukraine:*	**ТОВ «ХІЛІ ВОРЛД ЮКРЕЙН»** 01042, м. Київ, Україна, вул. Іоанна Павла II, буд. 20 Код ЄДРПОУ 42998097 Тел.: +38 044 333 68 88 e-mail: sales.support.ru@healyworld.net ***HEALY WORLD UKRAINE LLC*** *01042,Ukraine, Kiev, 20 John Paul II Street* *Code 42998097* *Tel.: +38 044 333 68 88* *e-mail: sales.support.ru@healyworld.net*
Класифікація *Classification*	**Клас IIa** *Class IIa*
Процедура оцінки відповідності: Conformity Assessment Route:	**Додаток 6** до Технічного регламенту щодо медичних виробів, затверджений постановою Кабінету Міністрів України від 02.10.2013 № 753. ***Annex 6** to Technical regulations on Medical Devices, approved by Resolution of Cabinet of Ministers of 02.10.2013 № 753.*
Сертифікати: *Certificates:*	**Сертифікат відповідності № PR.XXX-XX** *Certificate of conformity №.: PR.XXX-XX* **Строк дії сертифіката відповідності 12.12.2022** *Certificate of conformity is valid until: 12.12.2022*
Призначений орган з оцінки відповідності та його ідентифікаційний код *Conformity assessment body with its identification number:*	**ТОВ «ІМПРУВ МЕДИКЕЛ»** *IMPROVE MEDICAL LLC* UA.TR.120

Хілі ГмбХ, декларує виконання основних вимог щодо медичного виробу, згідно Додатку 1 Технічного регламенту щодо медичних виробів, затвердженого Постановою Кабінету Міністрів України № 753 від 2 жовтня 2013 р.

Healy GmbH, hereby *declares the fulfillment of basic requirements for medical devices, according to Annex 1 of Technical Regulations on Medical Devices, approved by Decree of Cabinet of Ministers of Ukraine № 753 on 2 October 2013.*

Місце видачі: Кранцлін, Німеччина
Place of issue: Kränzlin, Germany

Healy GmbH
Schloss Kränzlin
Darritzer Str. 6
16818 Kränzlin, Germany

Підпис уповноваженої особи
Signature of Authorized person

Дата підпису: 25.05.2020
Date of signing: 25.05.2020

CEO, Jafarian, Babak
Назва посади, ПІБ
Position, Full Name

Дата: XX-XX-2020 *Date: XX-XX-2020*	**Редакція: 1.0** *Version: 1.0*	**Сторінка 1 із 1** *Page 1 of 1*

IMPROVEMEDICAL

СЕРТИФІКАТ ВІДПОВІДНОСТІ

Порядок проведення процедури забезпечення функціонування комплексної системи управління якістю (Додаток 6 Технічного регламенту щодо медичних виробів, затвердженого постановою Кабінету Міністрів України від 02.10.2013 № 753 (ТР)

Виробник: **Healy GmbH**
Хілі ГмбХ
Schloss Kränzlin, Darritzer Strasse 6, 16818 Kränzlin,
Germany
Шлос Кранцлін, Даррітцер штрассе 6, 16818 Кранцлін,
Німеччина

Уповноважений представник: **ТОВ «ХІЛІ ВОРЛД ЮКРЕЙН»**
01042, м.Київ, Україна, вул. Іоанна Павла II, буд. 20

Групи виробів: **Healy ™**
Пристрої для електростимуляції
Healy ™
Electro stimulation devices

Клас ризику: **IIa**

Призначений орган з оцінки відповідності Товариство з обмеженою відповідальністю «ІМПРУВ МЕДИКЕЛ» (ідентифікаційний номер № **UA.TR.120**) підтверджує, що зазначений виробник впровадив систему управління якістю щодо процесів виробництва та остаточної перевірки стосовно вказаних виробів у відповідності до пунктів 3-5 Додатка 6 ТР та яка є об'єктом періодичних наглядових аудитів згідно пунктів 8-11 Додатка 6 ТР.
Даний сертифікат чинний за умови дії сертифікату № 7426GB414180628 від 28.06.2018, виданого MEDCERT ZERTIFIZIERUNGS - UND PRÜFUNGSGESELLSCHAFT FÜR DIE MEDIZIN GMBH (ідентифікаційний номер 0482).

8О104
ДСТУ EN ISO/IEC 17021-1

1О304
ДСТУ EN ISO/IEC 17065

Підстава для видачі:
Звіт № PR.388/6-20 від 17.07.2020;
Рішення про видачу сертифіката № PR.388/7-20 від 21.07.2020.

Сертифікат № PR.279-20
Дійсний до 12 грудня 2022 р.
Видання № 1. Сертифіковано з 21 липня 2020 р.
Дата реєстрації 21 липня 2020 р.

Керівник органу з оцінки відповідності
_____ **С. М. Згонник**

ТОВ «ІМПРУВ МЕДИКЕЛ»

Місцезнаходження юридичної особи:
Україна, 01042, м. Київ, бульвар М. Приймаченко, 1/27, кімната 506-4

Місцезнаходження ООВ:
Україна, 04112, м. Київ, вул. Ризька 8-А, оф. 110

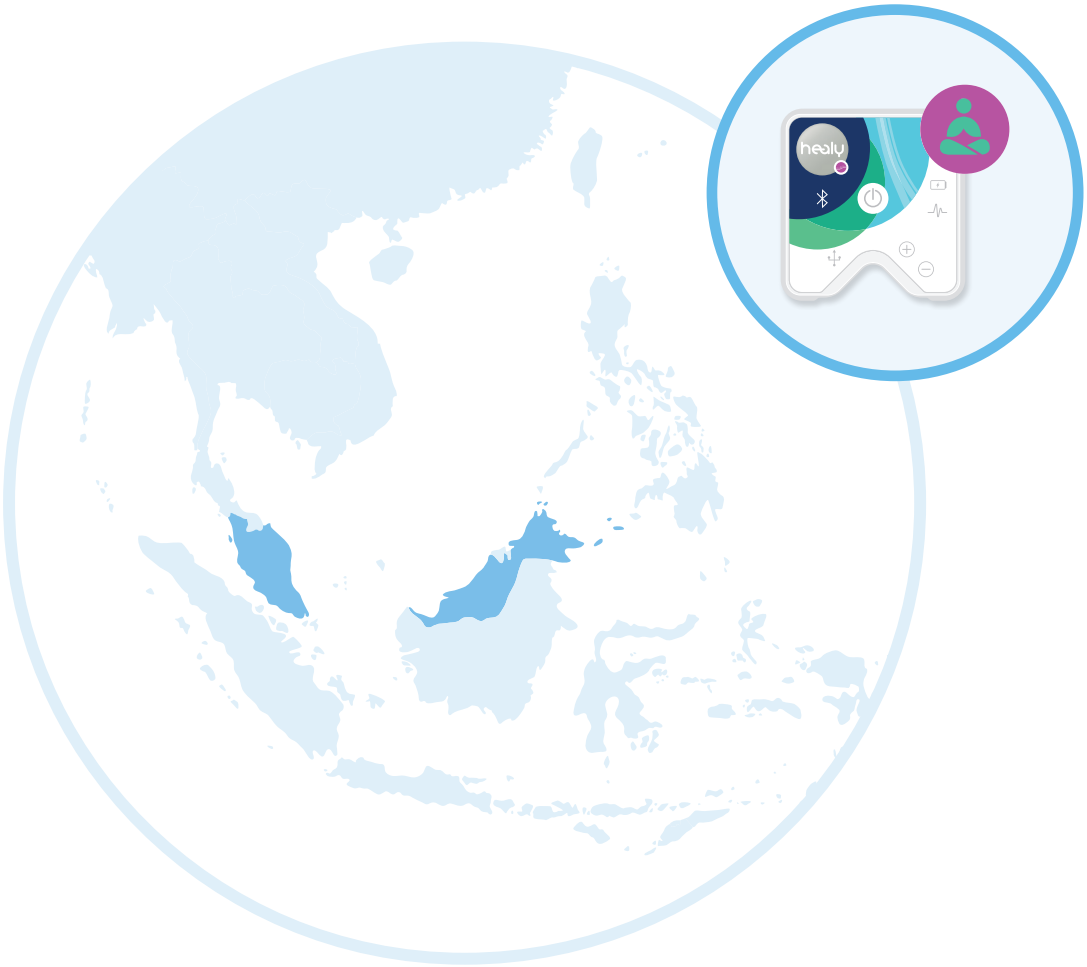
Сторінка 1 з 1

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:
Serial No.: 036247

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: **ANDAMAN MEDICAL BRIDGE SDN. BHD.**
This certificate is hereby issued to:

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: **HEALY GMBH SCHLOSS KRÄNZLIN, DARRITZER STRASSE 6 16818 KRÄNZLIN, GERMANY**
Name and address of manufacturer

,
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

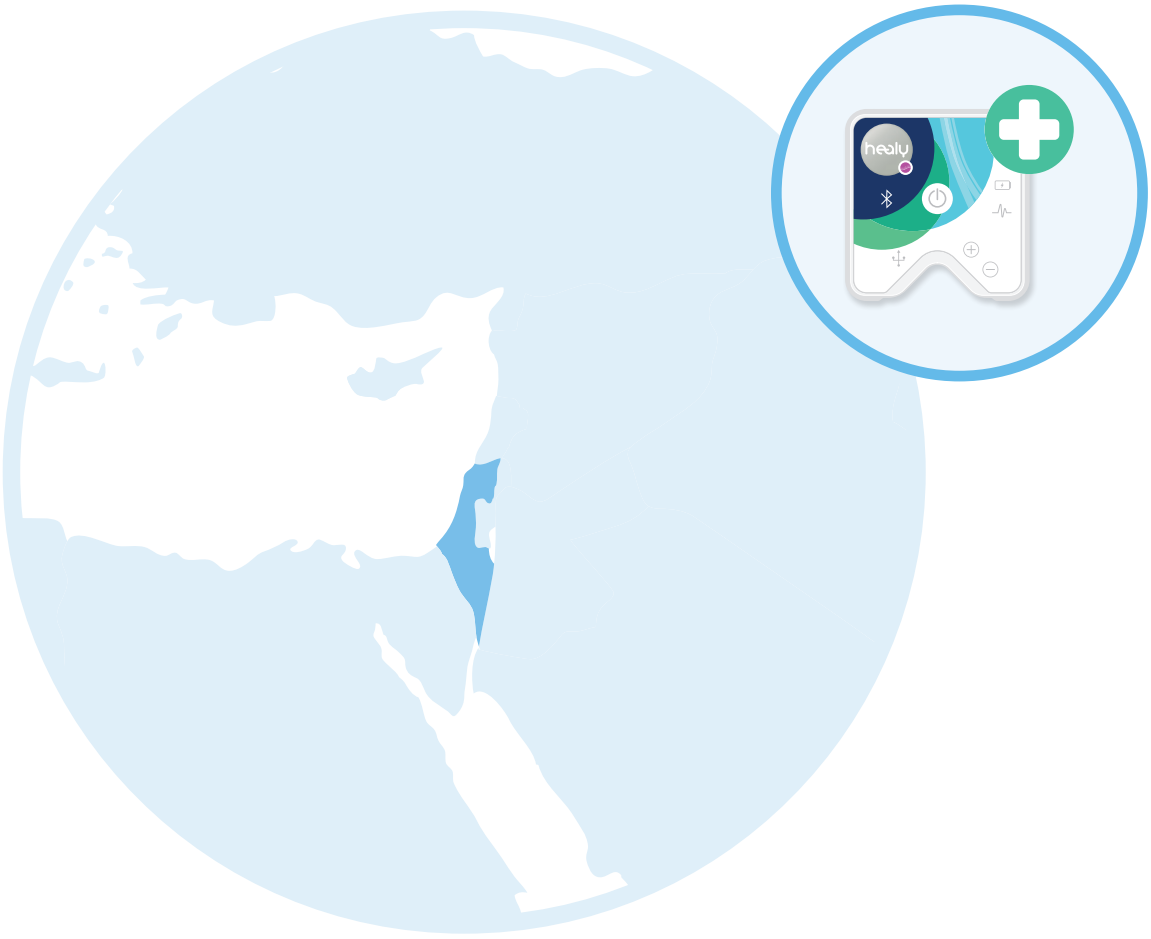
NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
6	Press button adhesive electrodes round Ø32 mm	108-4063	Self adhesive surface electrodes with button connector and 32mm diameter
7	Felts	108-4096	Felts that are placed on the ear electrodes
8	Charging cable USB 0.15 m	108-4068	Charging 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

מדינת ישראל
STATE OF ISRAEL

משרד הבריאות
חטיבת טכנולוגיות רפואיות, מידע ומחקר
אגף ציוד רפואי

אישור הגשת בקשה לחידוש רישום

מספר פניה	מספר רישום	תאריך הגשה
54415	**26760015**	**01/08/2022**

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

עבור הציוד הרפואי (אמ"ר) :

Healy

הילי

שם יצרן וכתובתו - **Healy GmbH ; Schloss Kranzlin, Darritzer Strase 6, 16818 Kranzlin ; GERMANY**

הערות:

01/08/2022
תאריך הדפסה

חתימה

משרד הבריאות
חטיבת טכנולוגיות רפואיות, מידע ומחקר
אגף ציוד רפואי

מדינת ישראל
STATE OF ISRAEL

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

אישור רישום בפנקס הציוד הרפואי

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

שם הציוד הרפואי	הילי Healy
קבוצות	1. Healy
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
התויה	1. כללית - 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.
שם בעל הרישום וכתובתו	דור שירותים פרמצבטיים בע"מ ; התע"ש 20, כפר סבא ; ישראל
שם היצרן וכתובתו	Healy GmbH ; Schloss Kranzlin, Darritzer Strase 6, 16818 Kranzlin ; GERMANY
שם אתר היצור וכתובתו	1. VTQ Videotronik GmbH, - Gruene Strage 2, 06268 Querfurt, Germany - GERMANY

התניות

הנחיות

- לפי הוראות היצרן שאושרו ע"י גוף המאשר: FDA, medcert'
- אישור בהתאם לאישור FDA/CE ומערכת איכות בתוקף.
- מאושר לשימוש בהתאם להוראות היצרן, כפי שאושרו ע"י הגופים המאשרים.
- יש לעמוד בהנחיות לסימון ציוד רפואי המיועד למשתמש הביתי.
- בעל הרישום (או היבואן) לא יחזיק מלאים אלא יבצע יבוא בשיטת "גב אל גב" (back to back) ישירות אל מוסדות הרפואה.

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

ד"ר נדב שפר מנהל אגף ציוד רפואי	31/01/2021	
שם ותפקיד המאשר	תאריך חתימת האישור	חתימה

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

GERMAS

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

A L A T K E S E H A T A N

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

KEMENTERIAN KESEHATAN REPUBLIK INDONESIA
Ditandatangani Secara Elektronik Oleh :
a.n Direktur Jenderal
Direktur Penilaian Alat Kesehatan dan PKRT
Dr. IGM. Wirabrata, Apt
NIP. 19751206 200312 1 001

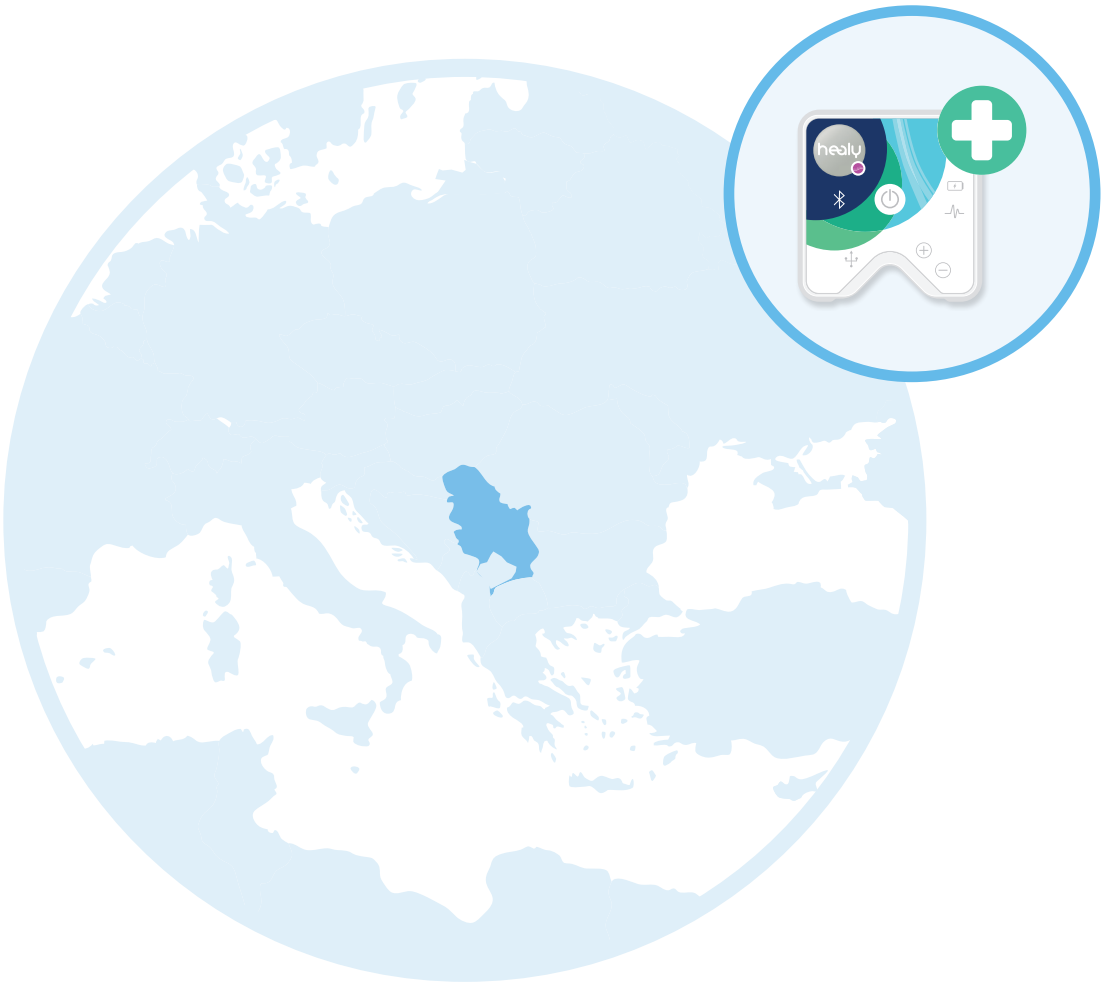
Catatan:
- UU ITE No 11 Tahun 2007 Pasal 5 ayat 1
  Informasi Elektronik dan/atau Dokumen Elektronik dan/atau hasil cetaknya merupakan alat bukti hukum yang sah.
- Dokumen ini telah ditandatangani secara elektronik menggunakan sertifikat elektronik yang diterbitkan BSrE.

Serbia

Healy with REF 0006 has medical device certification in Serbia 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 Serbia.



Република Србија
АГЕНЦИЈА ЗА ЛЕКОВЕ И
МЕДИЦИНСКА СРЕДСТВА СРБИЈЕ
Београд, Војводе Степе 458
Датум: 04.10.2019. године
Број: 515-02-02715-19-006

На основу члана 3. став 1. тачка 1) Закона о медицинским средствима („Службени гласник РС", бр. 105/2017) и члана 136. Закона о општем управном поступку („Службени гласник РС", бр. 18/2016) по захтеву **Pharmosis doo, Beograd (Zvezdara), Bulevar kralja Aleksandra 241/64** (у даљем тексту: подносилац захтева) број **515-02-02715-2019-7** од **30.08.2019.** године, директор Агенције за лекове и медицинска средства Србије (у даљем тексту: Агенција) издаје:

Р Е Ш Е Њ Е

1. **Региструју се медицинска средства** исте категорије, класе и произвођача, овлашћеног представника произвођача **Pharmosis doo, Beograd (Zvezdara), Bulevar kralja Aleksandra 241/64** и то:

а)

Редни број	Назив медицинског средства	Група генеричких медицинских средстава
1.	Healy	Aparat za elektrostimulaciju, za pacijenta

б) Категорија:
04 - Elektro-mehanička medicinska sredstva

в) Класа:
IIa

г) Произвођач:
Healy GmbH, Schloss Kranzlin, Darritzer Strasse 6, 16818 Kranzlin, Немачка

2. Решење о регистрацији медицинских средстава издаје се на рок важности од 60 дана након истека важности исправе о усаглашености и то до **10.02.2023.** године.

3. Медицинско средство из тачке 1. се издаје, односно продаје: на местима која су одређена дозволом

министарства надлежног за послове здравља о обављању промета на велико и промета на мало медицинских средстава, на основу прописа у области медицинских средстава и здравствене заштите.

О б р а з л о ж е њ е

Подносилац захтева **Pharmosis doo, Beograd (Zvezdara), Bulevar kralja Aleksandra 241/64** је поднео Агенцији захтев за регистарцију медицинских средстава исте категорије, класе и произвођача у Регистар медицинских средстава из тачке 1. овог решења.

Агенција је размотрила предметни захтев и документацију прописану одредбама чл. 9 и 10. Правилника о регистарцији медицинског средства ("Службени гласник РС", број 84/2018) и у складу са чланом 52. став 5. Закона о медицинским средствима, решила као у диспозитиву овог решења.

Против овог решења може се изјавити жалба Министарству здравља, Београд, Немањина 22 – 26, у року од 15 дана од дана пријема решења. Жалба се предаје непосредно Агенцији за лекове и медицинска средства Србије, као и првостепеном органу.

Решено у Агенцији за лекове и медицинска средства Србије под бројем **515-02-02715-19-006** од **04.10.2019.** године.

Решење доставити:
-Pharmosis doo, Beograd (Zvezdara), Bulevar kralja Aleksandra 241/64
- Архиви Агенције

в.д. директора
Спец. др. мед. Саша Јаћовић

Број: 515-02-02715-19-006 од 04.10.2019 године

523164

Страна 2 од 2

Healy International B.V.
Paterswoldseweg 806 | 9728 Groningen | Netherlands