

香港特別行政區政府
衛生署
醫療儀器管制辦公室
網站: www.mdco.gov.hk



Medical Device Control Office,
Department of Health,
Government of the Hong Kong
Special Administrative Region
Website: www.mdco.gov.hk

表列證書 CERTIFICATE OF LISTING

表列號碼
Listing No. : 140048

修訂本號碼
Revision No. : Nil

廠名、品牌及型號
Make, Brand Name and : Rehab-Robotics Hand of Hope
Model

儀器名稱
Device Description : Exercisers, Computer-Aided Training

製造商
Manufacturer : Rehab-Robotics Company Limited
Rm108A, Blk 9, 1/F, Enterprise Place, 5 Science Park West Ave, Hong Kong
Science Park, Shatin, N.T., Hong Kong

製造地點
Manufacturing Site : Rm108A, Blk 9, 1/F, Enterprise Place, 5 Science Park West Ave, Hong Kong
Science Park, Shatin, N.T., Hong Kong

本地負責人
Local Responsible Person : 復康機器人技術有限公司
Rehab-Robotics Company Limited

茲證明上述產品已在衛生署的「醫療儀器行政管理制度」中表列。上述本地負責人已由製造商委任，並承諾遵守「醫療儀器行政管理制度」的規定。

This is to certify that the product described above has been listed with the Department of Health under the Medical Device Administrative Control System (MDACS). The above Local Responsible Person has been designated by the Manufacturer and has undertaken to comply with the MDACS requirements.

發出日期
Date of issue : 26 February 2014

有效至
Valid until : 26 February 2019

衛生署署長
(李敏碧醫生代行)
(Dr Teresa LI)
for Director of Health

衛生署
醫療儀器管制辦公室

香港灣仔皇后大道東 183 號
合和中心 31 樓 3101 室



DEPARTMENT OF HEALTH
MEDICAL DEVICE CONTROL OFFICE

ROOM 3101, 31/F., HOPEWELL CENTRE,
183 QUEEN'S ROAD EAST, WAN CHAI
HONG KONG

本署檔號 OUR REF.: (17) in AN003820

來函檔號 YOUR REF.:

電話 TEL.: 3107 8484

傳真 FAX No.: 3157 1286

26 February 2014

Rehab-Robotics Company Limited
Flat/Rm 108A, Blk 9, 1/F, Enterprise Place 5,
Science Park West Avenue, Hong Kong Science Park,
Shatin, N.T., Hong Kong
(Attn: Mr Michael TSUI / Ms Hazel KWONG)

Dear Sir / Madam,

Application No. AN003820-
Listing under the Medical Device Administrative Control System

I refer to your above application for the listing of the following device:

Rehab-Robotics
Hand of Hope
Exercisers, Computer-Aided Training

It is my pleasure to inform you that your application has been approved. / ~~approved with the following conditions:~~^{*1*2}

I enclose herewith the Certificates of Listing for your retention. Please observe the *Code of Practice COP-01: Code of Practice for Local Responsible Persons* and *Guidance Notes GN-03: Adverse Incident Reporting by Local Responsible Persons*. The latest revisions of these documents can be downloaded from our website www.mdco.gov.hk.

The approval will be valid for 5 years provided that conditions specified above, if any, and all the listing requirements are complied with. I would like to remind you that failure to comply with any of the conditions or requirements may lead to cancellation of the listing.

Yours faithfully,

(Dr Teresa LI)
for Director of Health

/encl.

*1- delete as appropriate

*2- appeal against any conditions of approval shall be made to the Secretary to Medical Device Administration Appeal Committee within 4 weeks from the date of this letter

***We build a healthy Hong Kong and
aspire to be an internationally renowned public health authority***