香港特別行政區政府 衞生署 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.

180151

修訂本號碼

Revision No.

Nil

廠名、品牌及型號

Make, Brand Name and

Model

: SOMNOmedics SOMNOscreen plus, SOMNO HD

儀器名稱

Device Description

: Polysomnographs, Portable

製造商

SOMNOmedics GmbH

Manufacturer

Am Sonnenstuhl 63, 97236 Randersacker, Germany

製造地點

Manufacturing Site

Am Sonnenstuhl 63, 97236 Randersacker, Germany

本地負責人

康家醫療有限公司

Local Responsible Person

The HomeCare Medical Limited

茲證明上述產品已在衞生署的「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

: 11 June 2018

有效至

Valid until

: 11 June 2023

衞生署署長 (張勇仁醫生代行) (Dr Terence CHEUNG) for Director of Health