

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. : 140002

修訂本號碼  
Revision No. : b

廠名、品牌及型號  
Make, Brand Name and Model : DeVilbiss (see Certificate Attachment No.1 for model names(s) and product codes)

儀器名稱  
Device Description : Positive Airway Pressure Units, Continuous

製造商  
Manufacturer : DeVilbiss Healthcare LLC  
100 De Vilbiss Drive, Somerset, PA 15501, USA

製造地點  
Manufacturing Site : 100 De Vilbiss Drive, Somerset, PA 15501, USA


本地負責人  
Local Responsible Person : The HomeCare Medical Limited  
康家醫療有限公司

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 : 6 December 2018

有效至  
Valid until : 14 February 2024

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



衛生署 DEPARTMENT OF HEALTH

附件一 Attachment No. 1

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廠名及型號  
Make and Model : DeVilbiss (see below for model name(s) and product codes)

製造商  
Manufacturer : DeVilbiss Healthcare LLC

製造地點  
Manufacturing Site : (see Page One of Attachment No. 1)


發出日期  
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Manufacturing Site(s):  
100 De Vilbiss Drive, Somerset, PA 15501, USA

Model name(s) and product codes:

DeVilbiss SleepCube Standard CPAP (DV51UK), DeVilbiss BLUE Standard Plus CPAP (DV63E),  
DeVilbiss BLUE Auto Plus CPAP (DV64E), DeVilbiss SleepCube Standard Plus CPAP (DV53UK),  
DeVilbiss SleepCube AutoPlus CPAP (DV54UK), DeVilbiss SleepCube BiLevel S CPAP (DV55UK),  
DeVilbiss SleepCube BiLevel ST CPAP (DV56UK), DeVilbiss SleepCube AutoBilevel CPAP (DV57UK),  
DeVilbiss SleepCube Heated Humidification System (DV5HH), DeVilbiss SmartLink Module (DV5M)

-----End of List-----

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