



行政院衛生署

Department of Health
Taiwan, R.O.C.

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證明書 CERTIFICATE

Dec. 09, 2009

中華民國行政院衛生署茲證明：

THE DEPARTMENT OF HEALTH, TAIWAN, R.O.C., HEREBY CERTIFIES
THAT:

產品名稱 (NAMES OF PRODUCTS) 製造廠名稱 (NAME OF MANUFACTURER)

A 型肝炎標誌之體外診斷試劑套組 普生股份有限公司

(HAV SEROLOGICAL REAGENTS) GENERAL BIOLOGICALS CORP.

B 型肝炎標誌之體外診斷試劑套組

(HBV SEROLOGICAL REAGENTS) 製造廠地址 (ADDRESS OF MANUFACTURER)

C 型肝炎標誌之體外診斷試劑套組 新竹縣寶山鄉新竹科學園區創新一路 6 號

(HCV SEROLOGICAL REAGENTS) #6, INNOVATION FIRST ROAD,

愛滋病標誌之體外診斷試劑套組 SCIENCE-BASED INDUSTRIAL PARK, HSIN

(HIV SEROLOGICAL REAGENTS) CHU, TAIWAN, R.O.C.

上述產品之製造廠接受行政院衛生署定期或不定期稽核，且最近一次評鑑結果符合醫療器材優良製造規範（係參照 ISO13485 訂定）。

THE ABOVE-MENTIONED MANUFACTURING PLANT IS SUBJECT TO
INSPECTIONS AT APPROPRIATE INTERVALS. THE LAST SUCH INSPECTION
SHOWED THAT THE PLANT, AT THAT TIME, APPEARED TO BE IN
SUBSTANTIAL COMPLIANCE WITH CURRENT GOOD MANUFACTURING
PRACTICE REQUIREMENTS (BASED ON ISO13485) FOR THE PRODUCT(S)
LISTED ABOVE.

Chien Liang Lin

CHIEN-LIANG LIN
ON BEHALF OF SECTION-CHIEF, SECTION V
BUREAU OF PHARMACEUTICAL AFFAIRS