

中華民國行政院衛生署

DEPARTMENT OF HEALTH, THE EXECUTIVE YUAN
REPUBLIC OF CHINA

Date: JAN 16 2007

No: 023299

證明書

Certificate

茲證明下述醫療器材經行政院衛生署核准許可登記，准予產銷。

該醫療器材之製造廠亦經評定已實施經濟部與行政院衛生署聯合公布推行之醫療器材優良製造規範，並接受定期與不定期之稽查。

Department of Health, The Executive Yuan of the Republic of China hereby certifies that the medical device as described below is subject to its jurisdiction and is legally approved for manufacturing and distribution within the Republic of China.

It is also certified that the manufacturing establishment has been in compliance with the requirements for Good Manufacturing Practices as jointly promulgated by the Ministry of Economic Affairs and Department of Health, The Executive Yuan, R.O.C. and is subject to inspections at appropriate intervals.

製造廠名稱：康禾股份有限公司
Manufacturer: Konftec Corporation

製造廠地址：台北縣汐止市新台五路一段77號13樓-7
Manufacturing Plant Location: 13F-7, No.77, Sec.1, Sin-Tai 5th Road, Sijih City, Taipei County, Taiwan, R.O.C.

醫療器材名稱：“康禾”多頻道雷射治療儀 類別：第I類：一般及整型外科手術裝置
Device Name: “KONF” Multi-channel Laser Therapy System Classification: Category I: General and Plastic Surgery Devices

許可證字號：衛署醫器製字第002104號 核准日期：
Registration Number: DOH-MD-No. 002104 Date of Issue: Dec.15, 2006

處方、規格（型號）：
Formula、Model (Type): Aculas-AM, Aculas-HB, End of Products List.

效 能：
Intended Use: Blank.

Signed by Chi - Chou Liao
Director General
Bureau of Pharmaceutical Affairs -
for Sheng-Mou Hou M.D., Ph. D., M.P.H
Minister
Department of Health
The Executive Yuan, R.O.C.