

中華民國文件證明書 DOCUMENT AUTHENTICATION

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中華民國（臺灣）  
Republic of China (Taiwan)

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2. 簽署人  
has been signed by

連夢涵  
Lien, Meng-han

3. 簽署人職務  
acting in the capacity of

法院公證人  
Notary public

4. 用印人／單位  
bears the seal/stamp of

士林地方法院  
Shilin District Court

茲證明  
Certified

5. 地點  
at

台北  
Taipei

6. 日期  
the

November 14, 2017

7. 由  
by

外交部  
Ministry of Foreign Affairs

8. 案號  
Number

106100011023-002

9. 章戳  
Seal/stamp:

10. 簽署  
Signature:

Lin, Wei-ting  
Senior Officer, Bureau of Consular Affairs

For The Minister of Foreign Affairs

11. 附註：  
remarks:

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E003724





VĂN PHÒNG KINH TẾ - VĂN HÓA VIỆT NAM TẠI ĐÀI BẮC  
VIETNAM ECONOMIC AND CULTURAL OFFICE IN TAIPEI  
CHỨNG NHẬN/HỢP PHÁP HÓA LÃNH SỰ  
CONSULAR AUTHENTICATION

1. Quốc gia:  
Country VIỆT NAM  
Vietnam
2. do Ông (Bà):  
has been signed by Giấy tờ, tài liệu này  
This public document  
Lift, Wei-ting ký
3. với chức danh:  
acting in the capacity of Phó phòng, Cục Lãnh sự  
Deputy Director, Bureau of Consular Affairs
4. và con dấu của:  
bears the seal/stamp of Bộ Ngoại giao  
The Ministry of Foreign Affairs  
được chứng nhận/hợp pháp hoá lãnh sự  
Certified
5. tại: Đài Bắc  
at Taipei 6. ngày: 16/11/2017
7. Cơ quan cấp: Văn phòng Kinh tế - Văn hoá Việt Nam tại Đài Bắc  
by the Vietnam Economic and Cultural Office in Taipei
8. Số: 3547/2017

TL. Chủ nhiệm Văn phòng/For the Head of Office  
Trợ lý Chủ nhiệm/Assistant Head



中華民國衛生福利部

MINISTRY OF HEALTH AND WELFARE, REPUBLIC OF CHINA  
(TAIWAN)

Date: JAN 19 2016

No: 063707

證明書

Certificate

茲證明下述醫療器材經衛生福利部核准許可登記，准予產銷及輸出。  
該醫療器材之製造廠亦經評定已實施衛生福利部公布推行之  
醫療器材優良製造規範，並接受定期與不定期之稽查。  
Ministry of Health and Welfare, Republic of China (Taiwan) hereby certifies  
that the medical device as described below is subject to its jurisdiction and is legally  
approved in the Republic of China (Taiwan) to be manufactured, exported and freely sold.  
It is also certified that the manufacturing establishment has been in compliance with the  
requirements for Good Manufacturing Practices as promulgated by the Ministry of Health and Welfare,  
Republic of China (Taiwan) and is subject to inspections at appropriate intervals.



製造廠名稱及地址：理發實業有限公司(新北市鶯歌區建國路 190 號 4 樓)委託雅利企業股份有限公司(新北市林口區工九路 6 號)製造

Manufacturer and Manufacturing Plant Location: Manufactured by Acomed Industrial Co., Ltd. (No. 6, Kung 9 Rd, Lin-Kuo Dist., New Taipei City, Taiwan, R.O.C.) for AFa Industries Med Ltd. (4F., No. 190, Jianguo Rd., Yingge Dist., New Taipei City, Taiwan, R.O.C.)

醫療器材名稱："理發"外科手術燈

Device Name: "AFa" Surgical Lamp

類別：第 I 類：一般及整型外科手術裝置

Classification: Category I: GENERAL AND PLASTIC SURGERY DEVICES

許可證字號：衛部醫器製字第 005254 號

核准日期：105 年 1 月 12 日

有效日期：110 年 1 月 12 日

Registration Number: MOHW-MD-No. 005254

Date of Issue: Jan. 12, 2016

Date of Expiry: Jan. 12, 2021

處方、規格(型號)

Formula-Model( Type): ALA-01, ALA-100M/W/C, ALA-101C, ALA-300C, ALA-301C, ALA-303C, ALB-100M/C/W, ALB-101C, ALB-111C, K3-S/W, K3-1, K3-2, K3-3, K6-1, K6-2, K6-3, K6-1U, K6-2U, K6-3U, K6-S/W, K6+K3, End of Products List.

效能

Intended Use: Blank.

105士院認005

案號 Case No.: 000101 日期 Date: JAN 20 2016

本件 證明書 在臺灣士林地方方法  
院公證處認證。 公證人 連夢涵

This official document is attested at the Notary  
Public Office of Taiwan Zhihlin District Court,  
R.O.C.

Notary Public  
Lien, Meng-han

Signed by

Chiang Yu-Mei  
Director General  
Food and Drug Administration

for Been-Huang Chiang, Ph.D.  
Minister  
Ministry of Health and Welfare,  
Republic of China (Taiwan)