

中華民國衛生福利部

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

Date: NOV 04 2013

No: 051036

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經濟部與衛生福利部聯合公布推行之
醫療器材優良製造規範，並接受定期與不定期之稽查。
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 jointly promulgated by
the Ministry of Economic Affairs and Ministry of health and welfare,
Republic of China (Taiwan) and is subject to inspections at appropriate intervals.

製造廠名稱：聲博科技股份有限公司
Manufacturer: Broadsound Corporation

製造廠地址：新竹縣竹北市新泰路31號5樓
Manufacturing Plant Location: 5F, No. 31, Shintai Rd. Jupei City, Hsinchu County, Taiwan, R.O.C.

醫療器材名稱：“聲博”診斷用超音波探頭
Device Name: “Broadsound” Diagnostic Ultrasound Transducer

類別：第P類：放射學科用裝置
Classification: Category P: Radiology Devices

許可證字號：衛部醫器製字第003942號 核准日期：102年09月18日 有效日期：107年09月18日
Registration Number: MOHW-MD-No. 003942 Date of Issue: Sep. 18, 2013 Date of Expiry: Sep. 18, 2018

處方、規格（型號）
Formula・Model (Type): AC3C41A, AC7EC7A, AL3C114, AL3C119, AL3C123, AL3C126, AL3C130, AL3C34A, AL3C79B, AL3P299, AL5E12A, AL5E81A, AL6E124, AL7L24B, AL7L410, AL7L50A, AL8L543, AL8L545, AL8L546, AT3C42B, AT3C52B, AT3P32A, AT3P42A, AT5L40B, AT6C85B, AT6E84B, AT8L125, AT8L125-50, ES3P230, ES4C421, ES4C431, ES4C621, ES4C631, ES6C123, ES8L523, GC35C, GC35CS, GC3CRS, GC4C, GC4CA, GC4CRS, GCAB25, GCAB27, GE8C, GE8CRS, GL8LRS, GLSP1016, GLSP410, GLSP612, GP3S, GP3SRS, HPC3540A, HPC3540B, HPC85E, HPL113, HPPS3, HPPS4, HTC314, HTC314Q, HTC314T, HTC514, M3C40ED, M3C40ELX8, M3C40EPX6, M3C40IR, M3P20AHX8, M5C50EP, M5C50EPX8, M5C50IM, M5C50X6, M5C50X8, M6E10EDX8, M7L40ED, M8L40ECX8, M8L40ED, M8L40IM, ME3C36B, ME3C40B, ME3C60B, ME5C50B, ME6C10B, ME6E10B, ME7L38B, PH3C52B, PH5C73B, PH6E94B, PH7L95B, SMC52A, SMCH41A, SMCH62A, SMEC94A, SML105A, SML135A, SML73A, TC366GM, TC375EM, TC375FA, TC375FM, TC375MA, TC375TB, TC621FV, TC621MV, TC651MV, TC661TV, TC745FV, TL1204TA, TL604TA, TL703FN, TL703MA, TL704TA, TL805FS, TL805MA, TL805TA, TP30TB, End of Products List.

效能
Intended Use: Blank.

Signed by Shiu-Ming Hsieh
Director General
Food and Drug Administration
for Wei-Ta Chiu, MD, Ph. D.
Minister
Ministry of Health and Welfare,
Republic of China (Taiwan)

102 衛部醫器製字第001-2593 號 日期: NOV 08 2013
No. 102-Hsin-Yuan-Jen-Tsu No.001 Data:
公文書在臺灣新竹地方法院公證處認證。
公證人: 李碧雲
This official document is attested at the Notary Public Office of Taiwan
Hsin-Chu District Court R.O.C.
Notary Public
BI-YUN LEE