

Certificate

The Certification Body of
TOV Rheinland LGA Products GmbH

hereby certifies that the organization
Broadsound Corporation
5F, No.31, Shintai Road
Jupei City, Hsinchu, 302
Taiwan

has established and applies a quality management system
for the following scope:

**Design and Development, Manufacture and Distribution of
Medical Diagnostic Ultrasound Transducer Assemblies**

Proof has been furnished that the requirements specified in

EN ISO 9001:2008

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-01-22
Certificate Registration No.: SY 60106245 0001
An audit was performed. Report No.: 10053249 001
This Certificate is valid until 2021-01-20

Certification Body

Date 2018-01-22



Songdi

TOV Rheinland LGA Products GmbH - TillystraRe 2 - 90431 Nurnberg

Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-valid1ty@de.tuv.com <http://www.tuv.com/safety>



Certificate

The Certification Body of
TOV Rheinland LGA Products GmbH

hereby certifies that the organization
Broadsound Corporation
5F, No. 31, Shintai Road
Jupei City, Hsinchu, 302
Taiwan

has established and applies a quality management system for medical devices
for the following scope:

**Design and Development, Manufacture and Distribution of
Medical Diagnostic Ultrasound Transducer Assemblies**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2012
EN ISO 13485:2012/AC:2012**

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-01-22
Certificate Registration No.: SX 60106244 0001
An audit was performed. Report No.: 10053249 001
This Certificate is valid until: 2021-01-20

Certification Body

Date 2018-01-22



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C E R T I F I C A T E
of Conformity



Registration No.: AK 50231474 0001

Report No.: 10027442 002

Holder: **Broadsound Corporation**
5F, No. 31, Shintai Rd.,
Jupei City, Hsinchu 302
Taiwan

Product: Medical Device
(Medical Diagnostic Ultrasound Transducer Assemblies)

Identification: AL3C123, AL8L546, AL8L545, AL3P299, AT8L125-50, ES8L523,
ES4C631, ES4C621, ES6C123, ES4C421, ES4C431, AC3C41A,
AC7EC7A

Tested acc. to: IEC 60601-1:1988+A1+A2

The certificate of conformity refers to the above mentioned product. This is to certify that the specimen is in conformity with the assessment requirement mentioned above. This certificate does not imply assessment of the production of the product and does not permit the use of a TÜV Rheinland mark of conformity.

Date 22.06.2012



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

C E R T I F I C A T E
of Conformity



Registration No.: AK 50231478 0001

Report No.: 10030165 002

Holder: **Broadsound Corporation**
5F, No. 31, Shintai Rd.,
Jupei City, Hsinchu 302
Taiwan

Product: Medical Device
(Medical Diagnostic Ultrasound Transducer Assemblies)

Identification: HPC3540A, HPC3540B, HPC85E, HPPS3, HPPS4, TL704TA,
TL1204TA, TL604TA, TL805TA, TL805FS, TL805MA, TC375TB,
GCAB27, M3C40IR, M5C50IM, M8L40IM, M5C50EP, ES3P230,
M3C40ED, M7L40ED, M8L40ED

Tested acc. to: IEC 60601-1:2005
EN 60601-1:2006

The certificate of conformity refers to the above mentioned product. This is to certify that the specimen is in conformity with the assessment requirement mentioned above. This certificate does not imply assessment of the production of the product and does not permit the use of a TÜV Rheinland mark of conformity.

Date 22.06.2012



Certification Body

W. Hsu
Dipl.-Ing. W. Hsu

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

