



EC Declaration of Conformity

Manufacturer:

BroadSound Corporation

5F, No. 31, Shintai Road, Jupei City,
Hsinchu 302, Taiwan
Website: www.broadsound.com.tw
Tel: 886-3-5539868
Fax: 886-3-5539808

whose single Authorized Representative:

MT Promedt Consulting GmbH
Altenhofstrasse 80 D-66386
St. Ingbert ,Germany
Website: www.mt-procons.com
Tel: +49(0)6894-581020
Fax:+49(0)6894-581021
DIMDI No.: DE/0000040838

We, the manufacturer, herewith declare that the products

Medical Diagnostic Ultrasound Transducer Assembly

Model Name: AL3C114, AL3C119, AL3C123, AL3C126, AL3C130, AL3C34A, AL3C79B,
AL3P299, AL5E12A, AL5E81A, AL6E118, AL6E124, AL7L24B, AL7L410, AL7L50A, AL7L710,
AL8L413, AL8L543, AL8L545, AL8L546, AT3C42B, AT3C52B, AT3P32A, AT3P42A, AT5L40B,
AT6C85B, AT6E84B, AT8L125, AT8L125-50, ES3P230, ES3P240, ES4C421, ES4C431, ES4C621,
ES4C631, ES5L522, ES5P122, ES6C123, ES6E123, ES8L523, GC15D, GC35C, GC35CS, GC3C,
GC3CRS, GC4C, GC4CA, GC4CD, GC4CRS, GC8C, GC8CRS, GCAB25, GCAB27, GE8C, GE8CRS,
GEIC59, GEIC59D, GL10L, GL11LD, GL12L, GL7L, GL8L, GL8LRS, GLSP1016, GLSP1016D,
GLSP410, GLSP612, GP3S, GP3SRS, GP5S, GP7S, HPC3540A, HPC3540B, HPC85E, HPL113,
HPPS3, HPPS4, HTC314, HTC314G, HTC314T, HTC514, HTC715, M3C40ED, M3C40ELX8,
M3C40EPX6, M3C40IR, M3P20AHX8, M5C50EP, M5C50EPX8, M5C50IM, M5C50X6,
M5C50X8, M6E10EDX8, M7L40ED, M8L40ECX8, M8L40ED, M8L40IM, ME3C36B, ME3C40B,
ME3C60B, ME5C50B, ME6E10B, ME7L38B, PH3C52B, PH5C73B, PH6E94B, PH7L95B,
PHC52U, PHC85UE, PHL125U, SMC52A, SMC62X3, SMC85X3, SMCH41A, SMCH52X3,
SMCH62A, SME94X3, SMEC94A, SML105A, SML105X3, SML135A, SML135X3, SML73A,
SMLA523, SMP42X3, SMP84X3, TC366GM, TC375EM, TC375FA, TC375FM, TC375MA,
TC375TB, TC601GV, TC621FV, TC621MV, TC651MV, TC661TV, TC745FV, TC781TV, TL1005TB,
TL1204TA, TL1204TB, TL604TA, TL703FN, TL703MA, TL704STB, TL704TA, TL805FS,
TL805MA, TL805TA, TP30TB.

device subcategory: MD 1202 imaging devices utilizing non-ionizing radiation

GMDN-Code: 40768

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to IIa according to Annex IX of the Directive 93/42/EEC. It bears the mark



The product concerned has been designed and manufactured under a quality management system according to Annex II, without the Annex II.4, of Directive 93/42/EEC, and the essential requirement of Annex I pertaining to medical devices

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH

Tillystraße 2

90431 Nürnberg

Country : Germany

Certificate No.: HD 60106243 0001

Effective date: 2016-01-22

Expiry date: 2021-01-20

following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC.

This declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

BroadSound Corporation

Hsinchu , Taiwan, 06-Aug-2019

Place ,

date

Legally binding signature, Function



Wen Pin Lai

Wen Pin Lai, Ph.D.

Deputy General Manager