# EC Certificate

## Directive 93/42/EEC Annex II, excluding Section 4
## Full Quality Assurance System
## Medical Devices

**Registration No.:** HD 60106243 0001

**Report No.:** 10053249 001

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

**Products:** Medical Diagnostic Ultrasound Transducer Assemblies

Replaces Approval, Registration No.: HD 60076546 0001

**Expiry Date:** 2021-01-20

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

**Effective Date:** 2016-01-22

**Date:** 2016-01-22

Notified Body
TÜV Rheinland LGA Products GmbH Zertifizierungsstelle
TÜVRheinland
S. Liu

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Digitally signed by Ermicev Alexandr
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