

EC Certificate

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

Registration No.: HD 6010

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

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

Notified Body

TÜVRheinland

Tifizierungs

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