

# EC Declaration of Conformity

Date: 2021-06-30

*Manufacturer:*

**Broadsound Corporation**

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*Authorized Representative:*

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**DIMDI No.:** DE/0000040838

We, the manufacturer, herewith declare that the products

**Medical Diagnostic Ultrasound Transducer Assembly**

**Model Name: ES8L523**

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 60146096 0001

**Effective date:** 2020-03-05

**Expiry date:** 2024-05-26

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

Place

Wen Pin LAI, Ph.D., General Manager