EC Declaration of Conformity

Manufacturer:
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whose single 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: 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.

Digitally signed by Ermicev Alexandr
Date: 2019.10.31 18:19:46 EET
Reason: MoldSign Signature
Location: Moldova

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

CE 0197

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

Wen Pin Lai

Wen Pin Lai, Ph.D.
Deputy General Manager

Legally binding signature, Function