## **INNER SOUND Tuning Forks FDA registered**

Our Tuning Forks are classified as a Type 1 Medical Device. This means they are low risk and have fewer regulatory burdens than invasive medical devices.

Both FDA registration and CE (European Union) certification have annual fees. Both require extensive product evaluation, documented controls, risk analysis, demonstrated compliance with all applicable regulations, incident handling and reporting procedures. CE certification requires hiring of an Authorized Representative who is the control point for product notifications in Europe.

Both FDA registration and CE certification apply to medical instruments. Our tuning fork manufacturer, Riverbank Laboratories, is the only US tuning fork manufacturer we know of that has both designations.

Our tuning forks are applied in pairs, one at each ear, helping the body enter into a deep state of relaxation, supporting its own natural healing process.

They are precision-made to our frequencies in the US.