EU DECLARATION OF CONFORMITY

We, Amplivox Limited, declare under our sole responsibility that:

- The product detailed below including its accessories is in conformity with the essential requirements and provisions of Council Directive 93/42/EEC concerning Medical Devices, using procedures set out in Annex II (with the exception of Section 4), and Council Directive 2011/65/EU concerning the restriction of the use of certain hazardous substances in electrical and electronic equipment.

- The product detailed below complies with the following Standards:

IEC 60601-1:2005+A1:2012 EN 60601-1:2006+A1:2013	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014 EN 60601-1-2:2015	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
IEC/EN 60645-1:2017	Electroacoustics - Audiometric equipment - Part 1: Equipment for pure-tone and speech audiometry

- Our Quality Management System complies with the requirements of the Council Directive 93/42/EEC under the supervision of our Notified Body - TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany. The Notified Body identification number is 0123 and the associated EC Certificate number is G1 102264 0002.

Description of Equipment: Screening Audiometer

Model Number: Model 116

Product Type (93/42/EEC Annex IX classification): Type IIa

Signed:

Name of Signatory: Chris Roerig

Position: Regulatory Manager

Date: 1st March 2019