EU DECLARATION OF CONFORMITY

It has been demonstrated that:

Product:

Product type:	Diagnostic audiometer
Class:	IIa
Trademark:	Amplivox
Type No:	Model 240

Manufactured by: Amplivox Ltd
3800 Parkside, Solihull Parkway,
Birmingham Business Park,
Birmingham, B37 7YG
United Kingdom

EU Authorized Representative: DGS Diagnostics A/S
Audiometer Allé 1
5500 Middelfart
Denmark

is in conformity with the following Directives of the European Parliament and of the Council:

- 93/42/EEC of 14 June 1993, including all amendments, concerning Medical Devices, fulfilling the essential requirements in appendix I through application of a full quality system according to appendix II.3
- 2011/65/EU of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

The conformity is achieved by the fulfilling of the following main standards:

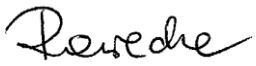
- IEC 60601-1:2005+A1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances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

Notified Body: TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 Munich, Germany
ID No. is 0123
EC Certificate number is G1 102264 0002 rev. 00

This declaration is made on the sole responsibility of:

Amplivox Ltd
3800 Parkside, Solihull Parkway,
Birmingham Business Park,
Birmingham, B37 7YG
United Kingdom
Tel. +44(0)1865 880846

Signature:



Name of Signatory: Patrycja Rawecka
Title: QA & RA Specialist
Date: 1st of March 2021