

EU DECLARATION OF CONFORMITY

It has been demonstrated that:

Product:

Product type: Screening audiometer
Product name: Model 116
Trademark: Amplivox
Class: IIa

Manufactured by:

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

EU Authorized Representative:

DGS Diagnostics A/S
Audiometer Allé 1
5500 Middelfart
Denmark

SRN:

To be determined later

is in conformity with the European Regulation (EU) 2017/745 and Directive 2011/65/EU.

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

G1 102264 0002

This declaration is made on the sole responsibility of:

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

Signature:



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