

## DECLARATION OF CONFORMITY

It has been demonstrated that:

Product name:	Otowave 202 & Otowave 202H
Intended purpose:	Tympanometer
Brand name:	Amplivox
Class:	Ila
Basic UDI-DI:	506048890_8502112_CX

## Manufactured by:

Name:	Amplivox Limited
Address:	3800 Parkside, Solihull Parkway Birmingham Business Park B37 7YG Birmingham
State/Country:	United Kingdom
Phone No.:	+44 (0)1865 880846
SRN:	GB-MF-000025632

## EU Authorized Representative:

Name:	DGS Diagnostics A/S
Address:	Audiometer Allé 1 5500 Middelfart
State/Country:	Denmark
Phone No.:	+45 3917 7500
SRN:	DK-AR-000020996

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

Conformity assessment:

Annex IX (Quality system and technical documentation assessment)

EU-Certificate number:

G1 102264 0002 rev. 00

Valid until:

2024-02-21

Notified Body:

TÜV SÜD Product Service GmbH  
Ridlerstraße 65, 80339 Munich, Germany  
ID No.: 0123

This declaration is made on the sole responsibility of:

Company:

Amplivox Limited

Address:

3800 Parkside, Solihull Parkway  
Birmingham Business Park

Address:

B37 7YG Birmingham

State/Country:

United Kingdom

Signature:



Name: Patrycja Rawecka

Title: Quality & Regulatory Specialist

Place: Birmingham

Date: 2022-07-06

(YYYY-MM-DD)