

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)