

## EU-MDR DECLARATION OF CONFORMITY

It has been demonstrated that:

<b>Product name:</b>	Model 116
<b>Intended purpose:</b>	Screening Audiometer
<b>Brand name:</b>	Amplivox
<b>Classification:</b>	Ila
<b>Basic UDI-DI:</b>	506048890_8000407_AK

### 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, RoHS Directive 2011/65/EU and REACH (EC) 1907/2006 Regulation.

**Conformity assessment:**

**MDR Certificate number:**

**Valid until:**

**Notified Body:**

Annex IX (Quality system and technical documentation assessment)

G10 102264 0006 Rev. 00

2029-06-27

TÜV SÜD Product Service GmbH

Ridlerstraße 65, 80339 Munich, Germany

ID No.: 0123

**This declaration is made on the sole responsibility of:**

**Company:**

Address:

Address:

State/Country:

Amplivox Limited

3800 Parkside, Solihull Parkway

Birmingham Business Park

B37 7YG Birmingham

United Kingdom

Signature:



Name: Patrycja Rawecka

Title: Regulatory & Quality Manager

Amplivox PRRC

Place: Birmingham

Date: 2024-07-01

(YYYY-MM-DD)