

## EU-MDR DECLARATION OF CONFORMITY

It has been demonstrated that:

**Product name:** Model 170  
**Intended purpose:** Screening Audiometer  
**Brand name:** Amplivox  
**Classification:** Ila  
**Basic UDI-DI:** 506048890\_8510384\_ED

**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:**

Annex IX (Quality system and technical documentation assessment)

**MDR Certificate number:**

G10 102264 0006 Rev. 00

**Valid until:**

2029-06-27

**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: Regulatory & Quality Manager

Amplivox PRRC

Place: Birmingham

Date: 2024-07-01

(YYYY-MM-DD)