

EU-MDR DECLARATION OF CONFORMITY

It has been demonstrated that:

Product name: Model 240
Intended purpose: Diagnostic Audiometer
Brand name: Amplivox
Classification: Ila
Basic UDI-DI: 506048890_8000403_A7

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)