



America

# CERTIFICATE

No. QS6 102264 0003 Rev. 04

**Certificate Holder:** **Amplivox Limited**  
3800 Parkside  
Solihull Parkway  
Birmingham Business Park  
Birmingham, West Midlands B37 7YG  
UNITED KINGDOM

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Manufacture, Distribution and Servicing of Audiometric Equipment for the area of Audiology**

**Standard(s):** **ISO 13485:2016**

**Regulatory Authority(ies):** **Australia TGA, Brazil ANVISA, Health Canada, Japan MHLW / PMDA, USA FDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:

[www.tuvsud.com/ps-cert?q=cert:QS6\\_102264\\_0003\\_Rev.04](http://www.tuvsud.com/ps-cert?q=cert:QS6_102264_0003_Rev.04)

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

**REPs Facility ID:** **F002643**  
**Report No.:** **713316113**  
**Effective Date:** **2024-05-08**  
**Expiry Date:** **2025-11-13**

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Date of Issue: 2024-05-14

( Renee Walker )  
Director, US Certification Body, MHS

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## Regulatory Requirements: Audit/Certification Criteria

### Australia

Therapeutic Goods (Medical Devices) Regulations 2002  
 - Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

### Brazil

- RDC ANVISA n. 665/2022 - Good Manufacturing Practices  
 - RDC ANVISA n. 551/2021  
 - RDC ANVISA n. 67/2009 - Vigilance

### Canada

- Medical Device Regulations – Part 1- SOR 98/282

### Japan

- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)  
 - Japan PMD Act (as applicable)

### United States

- 21 CFR Part 803  
 - 21 CFR Part 806  
 - 21 CFR Part 807 – Subparts A to D  
 - 21 CFR Part 820

## Facility(ies):

### Amplivox Limited

3800 Parkside, Solihull Parkway, Birmingham Business Park,  
 Birmingham, West Midlands B37 7YG, UNITED KINGDOM

### DGS Diagnostics Sp. z o. o.

Rosówek 43, 72-001 Kolbaskowo, POLAND

### DGS Diagnostics A/S

Audiometer Allé 1, 5500 Middelfart, DENMARK

### Diagnostic Group LLC

10393 West 70th Street, Eden Prairie, Minnesota, 55344, USA

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**Facility Scopes:**

**Amplivox Limited**

3800 Parkside, Solihull Parkway, Birmingham Business Park,  
Birmingham, West Midlands B37 7YG, UNITED KINGDOM

Design and Development, Distribution and Servicing of  
Audiometric Equipment

REPs Facility ID: F002643

**DGS Diagnostics Sp. z o. o.**

Rosówek 43, 72-001 Kolbaskowo, POLAND

Manufacture, Distribution and Servicing of Audiometric  
Equipment

REPs Facility ID: F005394

**DGS Diagnostics A/S**

Audiometer Allé 1, 5500 Middelfart, DENMARK

Design and Development, Manufacture of Audiometric  
Equipment

REPs Facility ID: F005395

**Diagnostic Group LLC**

10393 West 70th Street, Eden Prairie, Minnesota, 55344, USA

Manufacture, Distribution and Servicing of Audiometric  
Equipment

REPs Facility ID: F007315

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