



America

# CERTIFICATE

No. QS6 102264 0003 Rev. 01

**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 and Distribution of Audiometric Equipment**

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

**Regulatory Authority(ies):** **Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA. 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. Validity of this certificate can be obtained by visiting the website [www.tuvsud.com/ps-cert](http://www.tuvsud.com/ps-cert)  
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

**REPs Facility ID:** **F002643**

**Effective Date:** **2022-04-14**

**Expiry Date:** **2023-04-06**

Page 1 of 3

**Date of Issue:** 2022-04-19

( Renee Walker )  
Manager, US Certification Body,  
Medical and Health Services



America

# CERTIFICATE

No. QS6 102264 0003 Rev. 01

**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. 16/2013  
 - RDC ANVISA n. 23/2012  
 - RDC ANVISA n. 67/2009

**Canada**

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

**Japan**

- MHLW Ministerial Ordinance 169, Article 4 to Article 68  
 - PMD Act

**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.  
 ul. Zeusa 2, 72-006 Mierzyn, POLAND

DGS Diagnostics A/S  
 Audiometer Allé 1, 5500 Middelfart, DENMARK

Page 2 of 3

Date of Issue: 2022-04-19

( Renee Walker )  
 Manager, US Certification Body,  
 Medical and Health Services

# CERTIFICATE

No. QS6 102264 0003 Rev. 01

**Facility Scopes:**

**Amplivox Limited**

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

Headquarters  
REPs Facility ID: F002643

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

ul. Zeusa 2, 72-006 Mierzyn, POLAND

Manufacture, Service and Calibration of Audiometric Equipment,  
Hearing Aid Analyzers and Vestibular Examination Units  
REPs Facility ID: F005394

**DGS Diagnostics A/S**

Audiometer Allé 1, 5500 Middelfart, DENMARK

Manufacture, Distribution, Service and Calibration of Audiometric  
Equipment, Hearing Aid Analysers, Vestibular Examination Units and  
related Applied Products  
REPs Facility ID: F005395

Page 3 of 3

Date of Issue: 2022-04-19



( Renee Walker )  
Manager, US Certification Body,  
Medical and Health Services