



America

CERTIFICATE

No. QS6 102264 0003 Rev. 02

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

REPs Facility ID: **F002643**

Effective Date: **2022-11-14**

Expiry Date: **2025-11-13**

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Date of Issue: 2022-11-17

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

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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. 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

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Facility Scopes:

Amplivox Limited

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Design and Development, Distribution
and Servicing of Audiometric Equipment
REPs Facility ID: F002643

DGS Diagnostics Sp. z o. o.

ul. Zeusa 2, 72-006 Mierzyn, POLAND

Manufacture, Distribution and Servicing
of Audiometric Equipment
REPs Facility ID: F005394

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Design and Development, Manufacture
of Audiometric Equipment
REPs Facility ID: F005395

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