



CERTIFICATE

No. QS6 102264 0003 Rev. 06

Certificate Holder:

Amplivox Limited
Geneva House
International Park
Starley Way
Birmingham, B37 7GN
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. 06](http://www.tuvsud.com/ps-cert?q=cert:QS6_102264_0003_Rev.06)

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

REPs Facility ID:

F002643

Report No.:

713388710

Effective Date:

2026-09-02

Expiry Date:

2028-11-13

(Sofia Epshtein Elbrus)
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

Geneva House, International Park, Starley Way, Birmingham, B37 7GN, 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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Date of Issue: 2026-09-15



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Facility Scopes:

Amplivox Limited

Geneva House, International Park, Starley Way, Birmingham,
B37 7GN, UNITED KINGDOM

Distribution 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



(Sofia Epshtein Elbrus)
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