



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 102264 0004 Rev. 05

Holder of Certificate: **Amplivox Limited**
Geneva House
International Park
Starley Park
Birmingham, B37 7GN
UNITED KINGDOM

Certification Mark:



Scope of Certificate: **Design and development, manufacture, sales and servicing of audiometric equipment for the area of audiology**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 102264 0004 Rev. 05

Report No.: 713354794 - 713388710

Valid from: 2025-12-22
Valid until: 2028-12-21

Date, 2025-12-02

Christoph Dicks
Head of Certification/Notified Body



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Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **Amplivox Limited**
Geneva House, International Park, Starley Park, Birmingham, B37
7GN, UNITED KINGDOM

Design and development, marketing, sales and servicing of
audiometric equipment

DGS Diagnostics Sp. z o. o.
Rosówek 43, 72-001 Kolbaskowo, POLAND

Manufacture, distribution and servicing of audiometric equipment

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

Design and development, manufacture of audiometric equipment

Diagnostic Group LLC
10393 West 70th Street, Eden Prairie, Minnesota, 55344, USA

Manufacture, distribution and servicing of audiometric equipment