



EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 102264 0006 Rev. 00

Manufacturer:

Amplivox Limited

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

SRN Manufacturer - GB-MF-000025632

Authorized Representative:

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

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.

The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. 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:G10 102264 0006 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:G10_102264_0006_Rev._00)

Report No.: 713249001

Valid from: 2024-06-28

Valid until: 2029-06-27

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-06-28



Benannt durch/Designated by
 Zentralstelle der Länder
 für Gesundheitsschutz
 bei Arzneimitteln und
 Medizinprodukten
 www.zfg.de
 BS-MDR-099



Product Service

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Classification: Class IIa
Device Group: Z121401 - AUDIOMETERS
 Z121490 - VARIOUS ENT INSTRUMENTS
Intended Purpose: -

The validity of this certificate depends on conditions and/or is limited to the following: -none-

Revision History:

Rev.	Dated	Report	Description
00	2024-06-28	713249001	Initial issuance