



EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 102264 0002 Rev. 00

Manufacturer:**Amplivox Limited**

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

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

Product Category(ies): Audiometric Equipment

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713146975

Valid from: 2019-02-22

Valid until: 2024-02-21

Date, 2019-02-22

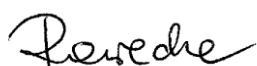
I. Permit

Stefan Preiß

CE Type List

The following Amplivox products are CE marked and covered by the EC Certificate G1 102264 0002 Rev. 00

Product Name	Product Description	Class, rule	GMDN/CND	Remarks
Model 116	Screening Audiometer	Ila, rule 10	63545/ Z121401	
Model 170	Screening Audiometer	Ila, rule 10	63545/ Z121401	
PC850	Automatic Audiometer	Ila, rule 10	63545/ Z121401	
Otosure	Automatic Audiometer	Ila, rule 10	63545/ Z121401	
modelONE	Screening Audiometer	Ila, rule 10	63545/ Z121401	
Model 240	Diagnostic Audiometer	Ila, rule 10	63545/ Z121401	
Model 260	Diagnostic Audiometer	Ila, rule 10	63545/ Z121401	
Model 270	Diagnostic Audiometer	Ila, rule 10	63545/ Z121401	
Model 270+	Diagnostic Audiometer	Ila, rule 10	63545/ Z121401	
Otowave 102	Impedance Audiometer	Ila, rule 10	63545/ Z12149005	
Otowave 102-C	Impedance Audiometer	Ila, rule 10	63545/ Z12149005	
Otowave 202 and Otowave 202H	Impedance Audiometer	Ila, rule 10	63545/ Z12149005	
Otowave 302	Impedance Audiometer	Ila, rule 10	63545/ Z12149005	
Otowave 302+	Impedance Audiometer	Ila, rule 10	63545/ Z12149005	



Birmingham, 2022-07-29

Patrycja Rawecka, RA&QA Specialist