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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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Product Service

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

Stefan Preiß

TÜV SÜD
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT

CE Type List

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

Product Name	Product Description	MDD Class	Sterile Yes/No	CE Mark Start Date
Model 116	Screening Audiometer	Ila	No	Jan 2002
Model 170	Automatic Audiometer	Ila	No	Jul 2005
PC850	Automatic Audiometer	Ila	No	Dec 2001
CA850	Automatic Audiometer	Ila	No	Jan 2007
Otosure	Automatic Audiometer	Ila	No	Jul 2012
Model 240	Diagnostic Audiometer	Ila	No	Feb 2001
Model 260	Diagnostic Audiometer	Ila	No	Feb 2000
Model 270	Diagnostic Audiometer	Ila	No	Mar 2002
Otowave 102	Tympanometer	Ila	No	Jul 2007
Otowave 202	Tympanometer	Ila	No	Jul 2013
Otowave 302	Tympanometer	Ila	No	Sep 2016

Birmingham, UK
27th February 2019



Chris Roerig

amplivox

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