

EC Certification

Intertek

FULL QUALITY ASSURANCE SYSTEM
Directive 93/42/EEC for Medical Devices, Annex II excluding (4)

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0473 marking on those products listed below.

AMPLIVOX LIMITED

6 Oasis Park, Eynsham, Oxfordshire, OX29 4TP, United Kingdom

Audiometric Equipment

See attached product schedule

Certificate Number: 851-01 CE
Initial Certification Date: 09 December 2008
Certificate Effective Date: 23 October 2014
Certificate Expiry Date: 08 December 2018



Brian Johnson
AMTAC Certification Services Limited, Milton Keynes, UK
This certificate is the property of AMTAC Certification Services Ltd



In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone.

This Certificate is for the exclusive use of AMTAC's client and is provided pursuant to the agreement between AMTAC and its Client. AMTAC's responsibility and liability are limited to the terms and conditions of the agreement. AMTAC assumes no liability to any party, other than to the Client in accordance with the agreement, for any loss, expense or damage occasioned by the use of this Certificate. Only the Client is authorized to permit copying or distribution of this Certificate. Any use of the AMTAC name or one of its marks for the sale or advertisement of the tested material, product or service must first be approved in writing by AMTAC.

The certificate remains the property of Intertek, to whom it must be returned upon request.

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

AMTAC Certification Services Limited is a Notified Body according to Directive 93/42/EEC for medical devices, with identification number 0473.

PRODUCT SCHEDULE FOR CERTIFICATE 851-01 CE AMPLIVOX LIMITED

Intertek

Product Name	Product Description	MDD Product Classification	Sterile Yes/No
Model 116	Screening Audiometer	Class IIa	No
Model 170	Automatic Audiometer	Class IIa	No
PC850	Automatic Audiometer	Class IIa	No
CA850	Automatic Audiometer	Class IIa	No
Otosure	Automatic Audiometer	Class IIa	No
Model 240	Diagnostic Audiometer	Class IIa	No
Model 260	Diagnostic Audiometer	Class IIa	No
Model 270	Diagnostic Audiometer	Class IIa	No
Otowave 102	Tympanometer	Class IIa	No
Otowave 202	Tympanometer	Class IIa	No

Initial Certification Date: 09 December 2008
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Brian Johnson ~ Authorized Signatory