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Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
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ZLG-BS-244.10.08



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

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 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT