Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
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 044841 0022 Rev. 00

Manufacturer: **Interacoustics A/S**
Audiometer Allé 1
5500 Middelfart
DENMARK

Facility(ies):
Interacoustics A/S
Audiometer Allé 1, 5500 Middelfart, DENMARK

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, Hearing Aid Analysers, Vestibular Examination Units**

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.: 713130805

Valid from: 2018-10-01
Valid until: 2023-09-30

Date, 2018-08-31

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD
A4 / 07.17