



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 13 05 44841 011

Manufacturer: **Interacoustics A/S**
Drejervaenget 8
5610 Assens
DENMARK

Facility(ies): Interacoustics A/S
Drejervaenget 8, 5610 Assens, DENMARK

Sanibel Supply A/S
Drejervaenget 8, 5610 Assens, DENMARK

Product Category(ies): **Audiometric Equipment,
Hearing Aid Analysers,
Vestibular Examination Units,
Nasal and Upper Airway Diagnosis Devices**

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.: 713023569/-1

Valid from: 2013-10-01

Valid until: 2018-09-30

Hans-Heiner Junker



Date, 2013-08-28

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

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