



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 11 06 63429 001

Manufacturer: **MAICO Diagnostic GmbH**
Salzufer 13/14
10587 Berlin
GERMANY

Facility(ies): MAICO Diagnostic GmbH
Salzufer 13/14, 10587 Berlin, GERMANY

MAICO Diagnostic GmbH
Zum Lonnenhohl 5, 44319 Dortmund, GERMANY

Product Category(ies): **Subjective Audiometer, Objective Audiometer, Impedance Meter**

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.: 71386012

Valid from: 2011-07-09
Valid until: 2016-07-08



Hans-Heiner Junker

Date, 2011-07-05

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

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