

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 14 10 76081 006

Manufacturer:

Auditdata A/S

Dalbergstroeget 5-7 2630 Taastrup DENMARK

Facility(ies):

Auditdata A/S

Dalbergstroeget 5-7, 2630 Taastrup, DENMARK

Product Category(ies):

Hearing aid analyzer; Audiometer

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.:

713050241/-1

Valid from: Valid until: 2014-12-11 2019-12-10



Date, 2014-12-01





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