

Declaration of Conformity

According to Medical Device Directive (MDD) 93/42/EEC

Manufacturer

Auditdata A/S
Dalbergstrøget 5-7
2630 Taastrup
Denmark

Conformity Assessment Procedure

Annex II.3 excluding (4) of the Medical Device Directive
MDD 93/42/EEC

Notified Body

TÜV SÜD Product Service GmbH
Ridlerstr. 65
80339 München



Product Identification

Category:	Audiometers and Associated Accessories
Brand:	OTOPod
Model:	M1, M2
Lot/Batches/Serial number:	All issued serial numbers from M1: 28000001 M2: 29000001

MDD Directive

Class IIa, Rule 10, MDD
93/42/EEC

The medical device compliance with the essential requirements in accordance with Annex I of the Medical Device Directive 93/42/EEC.

We declare under our sole responsibility that the products, to which this declaration relates, are in conformity with the Essential Requirements Annex I of the above directive.

This DOC is Valid until May 11th 2021 - EC certificate validity date.

Taastrup, August 2nd 2018

Dan Haugbøl, Corporate QA & Regulatory Manager



Signature