

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:	Hearing Medical Diagnostic
Brand:	Primus
Model:	2000 Primus Audiometer Unit Ice
Lot/Batches/Serial number:	All issued serial numbers from 26000001.

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 December 10th 2019 - EC certificate validity date.

Taastrup, August 2nd 2018

Dan Haugbøl, QA & Regulatory Manager



Signature