

Auditdata

DECLARATION OF CONFORMITY

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

Manufacturer Auditdata A/S
Dalbergstroeget 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 FITTING UNIT PRO
Lot/Batches/Serial number:	All issued serial numbers from 25000001

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 26th 2024 - EC certificate validity date.

Taastrup, December 11th 2020

Dan Haugbøl, Director QA/RA & IT Information security

Signature