



## 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:	PRIMUS FITTING UNIT+ (PFU+)
Lot/Batches/Serial number:	All issued serial numbers from 21000001.

### 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 26<sup>th</sup> 2024 - EC certificate validity date.

Taastrup, December 2<sup>nd</sup> 2019

Dan Haugbøl, Director QA/RA & IT Information security

Signature