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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

CE 0123

Product Identification

Category:	Hearing Medical Diagnostic
Brand:	Primus
Model:	Primus Fitting Unit (PFU)
Lot/Batches/Serial number:	All issued serial numbers from 00734.

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 2nd 2019
Dan Haugbøl, Director QA/RA & IT Information security

Signature