auditdata

Your Partner in Audiology Solutions

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 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 December 10th 2019 - EC certificate validity date.

Taastrup, August 2nd 2018

Dan Haugbøl, QA & Regulatory Manager

Signature