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 CE 0123
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 May 26th 2024 - EC certificate validity date.

Taastrup, December 11th 2020

Dan Haugbøl, Director QA/RA & IT Information security

Signature

ID: DN00625/05