


Auditdata

DECLARATION OF CONFORMITY

Manufacturer	Auditdata A/S Wildersgade 10B 1408 Copenhagen 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	MD Category: Hearing Medical Diagnostic (Hardware)
	Brand: Entomed
	Type Model: SA 201
	SRN: -
	UDI/DI: 05711781DHF2009ZW
	Lot/Batches/Serial number: All issued serial numbers from ED152001
Risk classification	MDD 93/42/EEC Class IIa, Rule 10

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.

Copenhagen, June 8th 2021

Dan Haugbøl, Director QA/RA & IT/CSO



Signature