

Auditdata

DECLARATION OF CONFORMITY

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT

Manufacturer name and address	Auditdata A/S Wildersgade 10B 1408 Copenhagen Denmark	
Notified Body name and address	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 München	 0123
Product Identification	MD Category: Trademark: Type/Model: CS (Common specification) SRN: Basic UDI-DI: Risk class: Lot/Batches/Serial number:	Hearing Medical Diagnostic (Hardware) Entomed Audiometer SA 201 N/A no common specification has been published DK-MF-000011415 05711781DHF2009ZW IIa, rule 10 All issued serial numbers from ED152001
Intended purpose	Audiometer is a device used for evaluating hearing acuity. The audiometer records the subject's responses to produce an audiogram of threshold sensitivity, or speech understanding profile.	
Conformity assessment	Annex IX (Quality system and technical documentation assessment)	
EC-Certificate No.:	G10 076081 0015	
DOC valid until	2029-02-18	

This declaration of conformity is issued under the sole responsibility of Auditdata A/S. We hereby declare that the medical device specified above is in conformity with the European Regulation (EU) 2017/745 and Directive 2011/65/EU.

Copenhagen, February 20th 2024

Denys Lebedev, QA/RA Manager

