

# Auditdata

## DECLARATION OF CONFORMITY

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT

<b>Manufacturer name and address</b>	Auditdata A/S Wildersgade 10B 1408 Copenhagen Denmark	
<b>Notified Body name and address</b>	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 München	 0123
<b>Product Identification</b>	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 204 N/A no common specification has been published DK-MF-000011415 05711781DHF2009ZW IIa, rule 10 All issued serial numbers from EG152001
<b>Intended purpose</b>	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.	
<b>Conformity assessment</b>	Annex IX (Quality system and technical documentation assessment)	
<b>EC-Certificate No.:</b>	G10 076081 0015	
<b>DOC valid until</b>	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 20<sup>th</sup> 2024**

Denys Lebedev, QA/RA Manager

