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	CE 0123
Product Identification	MD Category:	Hearing Medical Diagnostic (Hardware and Software)
	Trademark:	Measure, Unity 4
	Type/Model:	2000-1 Fitting Unit (2000-1 FU)
	CS (Common specification)	N/A no common specification has been published
	SRN:	DK-MF-000011415
	Basic UDI-DI:	05711781DHF2000ZC
	Risk class:	IIa, rule 10
	Lot/Batches/Serial number:	All issued serial numbers for 2000-1 FU from 33000001
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. The 2000-1 FU with stated accessories is indicated for non-continuous, noninvasive air and optionally bone conduction and speech audiometric testing. The 2000-1 FU is indicated for non-continuous real-ear measurements (REM) at the ear drum by means of noninvasive external ear canal insertion of a probe tube.	
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 19th 2024

Denys Lebedev, QA/RA Manager

ID: DN02476/02