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:	MD Data system (SaMD software modules)
	Trademark:	Auditbase
	Type Model:	2003 Auditbase
	Common specifications (CS):	N/A no common specification has been published
	SRN:	DK-MF-000011415
	Basic UDI-DI:	05711781DHF2003-12Z
	MDR Risk class:	Class IIb, Rule 11
	Lot/Batches/Serial number:	From software release 6.5.0
Intended purpose	Auditbase is an audiological "**Hospital Information System**" • For storage and transfer of electronic patient records, archiving of documents and data related to a specific patient. • Various modules for recording, viewing and altering of clinical patient data. • The stored information is partly intended for aiding in decision making for correct treatment.	
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.

Copenhagen, October 21, 2024
Denys Lebedev, QA/RA Manager

Signature

ID: 10.0085/05