Auditdata

DECLARATION OF CONFORMITY

In the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices

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
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
	MDD Risk class:	Class I, Rule 12
	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.

https://www.tuvsud.com/ps-cert?q=CL+076081+0016+Rev.+01

Article number:
2003 Auditbase (Auditbase)
05711781002064

DOC valid until 2028-06-30

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) in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745.

Copenhagen, June 14th 2024

Denys Lebedev, Manager QA/RA

Signature

ID: 10.0085/05