ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 076081 0015 Rev. 01

Manufacturer:

Auditdata A/S
Wildersgade 10B
1408 Copenhagen
DENMARK

SRN Manufacturer - DK-MF-000011415

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 076081 0015 Rev. 01

Report No.:	713217412
Preceding Certificate No.:	G10 076081 0015 Rev. 00
Valid from:	2024-10-21
Valid until:	2029-02-18
Date of Initial Issuance:	2024-02-19

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-10-21

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Classification:	Class IIa
Device Group:	Z121401 - AUDIOMETERS
Intended Purpose:	-

Classification:	Class IIb
Device Group:	Z12149092 - VARIOUS ENT INSTRUMENTS - MEDICAL DEVICE SOFTWARE
Intended Purpose:	The medical device is intended for storage and transfer of electronic patient records, archiving of documents and data related to a specific patient and for aiding in decision making for correct treatment.

The validity of this certificate depends on conditions and/or is limited to the following:	-

Revision History:

Rev.	Dated	Report	Description
00	2024-02-19	713275326 / 713307646	Initial issuance
01	2024-10-21	713217412	Supplemented: Device(s)/group of device(s) added

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