MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 076081 0013 Rev. 00

Certificate Holder: **Auditdata A/S**
Dalbergstroeget 5-7
2630 Taastrup
DENMARK

Certification Mark:

Scope of Certificate: **Design and Development, Production, Distribution and Servicing of Audiometric Equipment**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Health Canada, USA FDA, MHLW / PMDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website https://www.tuev-sued.de/product-testing/certificates

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: **31-038-5849**

Effective Date: **2019-07-11**

Expiry Date: **2022-07-10**

Date of Issue: 2019-07-17

(Dawn M. Tibodeau)
Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

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Regulatory Requirements:	**Audit/Certification Criteria**
	Australia Therapeutic Goods (Medical Devices) Regulations 2002 - Schedule 3, Part 1
	Canada - Medical Device Regulations SOR/98-282, Part 1
	United States - 21 CFR Part 803 - 21 CFR Part 806 - 21 CFR Part 807 - 21 CFR Part 820
	Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68 - PMD Act
Facility(ies):	Auditdata A/S Dalbergstroeget 5-7, 2630 Taastrup, DENMARK
Facility Scopes:	Design and Development, Production, Distribution and Servicing of Audiometric Equipment DUNS No: 31-038-5849

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