

TEST REPORT

An Accredited Technical Test Executed under the Danish Accreditation Scheme

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Prøvningsrapport

for akkrediteret prøvning i henhold til Dansk Akkrediterings Ordning


No. of annexes 1
Antal bilag

Test-report No <i>Prøvningsrapport Nr.</i>	UPRR020008-01	Our reference <i>Vor reference</i>	Finn Christian Boll	Copy No <i>Eksemplar Nr.</i>	1
Equipment <i>Udstyr</i>	Medical Bluetooth device				
Manufacture <i>Fabrikat</i>	GN Otometrics A/S				
Type <i>Type</i>	NOAHlink				
Serial No <i>Serie Nr.</i>	-	Equipment received <i>Udstyr modtaget</i>	31.01.2002		

Client <i>Rekvirent</i>	GN Otometrics A/S				
Address <i>Adresse</i>	Dybendalsvænget 2,				
Postal code <i>Post Nr.</i>	2630	City <i>By</i>	Tåstrup	Country <i>Land</i>	Danmark

The testing has been carried out in accordance with <i>Prøvningen er udført i henhold til</i>	ETS 300 328 (November 1996)				
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Remarks <i>Bemærkninger</i>	All the tested parameters fulfil the requirements				
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Date and signature <i>Dato og underskrift</i>	31 maj 2002 				
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Finn C. Boll
Test Engineer

The test result is only valid for the equipment tested.

Prøvningsresultatet gælder kun for det afprøvede udstyr.

The test report shall not be reproduced except in full without the written permission of Telelaboratoriet, and no part shall be quoted out of context

Prøvningsrapporten må kun gengives i uddrag, såfremt Telelaboratoriet skriftligt har godkendt dette.

DANAK (DANSK Akkreditering)

DANAK blev etableret i 1991 med hjemmel i lov nr. 394 om erhvervsfremme af 13. juni 1990.

Kravene til akkrediterede prøvningslaboratorier er fastlagt i Erhvervsfremme Styrelsens bekendtgørelse om akkreditering af laboratorier til teknisk prøvning m.v., samt til GLP-inspektion. Bekendtgørelsen henviser til andre dokumenter, hvor akkrediteringskriterierne er beskrevet yderligere.

Standarderne DS/EN ISO/IEC 17025 "Generelle krav til prøvnings- og kalibreringslaboratoriernes kompetence" og DS/EN 45002 "Generelle kriterier for bedømmelse af prøvningslaboratorier" beskriver grundlæggende akkrediteringskriterier. DANAK anvender fortolkningsdokumenter til de enkelte krav i standarderne, hvor det skønnes nødvendigt. Disse vil hovedsageligt være udarbejdet af "European co-operation for Accreditation (EA)" eller "International Laboratory Accreditation Co-operation (ILAC)" med det formål at opnå ensartede kriterier for akkreditering på verdensplan. DANAK udarbejder desuden tekniske forskrifter vedr. specifikke krav til akkreditering, som ikke er indholdt i standarderne.

For at et laboratorium kan være akkrediteret kræves blandt andet:

- at laboratoriet og dets personale skal være fri for enhver kommerciel, økonomisk eller anden form for pression, som kan påvirke deres tekniske dømmekraft.
- at laboratoriet har et dokumenteret kvalitetsstyrings-system.
- at laboratoriet råder over prøveteknisk udstyr og lokaler af en tilstrækkelig standard til at kunne udføre den prøvning som laboratoriet er akkrediteret til.
- at laboratorieledelse og -personale har såvel faglig kompetence som praktisk erfaring i udførelsen af den prøvning som laboratoriet er akkrediteret til.
- at der er indarbejdet faste rutiner for sporbar kalibrering og usikkerhedsbestemmelse.
- at akkrediteret teknisk prøvning udføres efter fuldt validerede og dokumenterede metoder.
- at laboratoriet skal registrere forløbet af akkrediteret prøvning således, at dette kan rekonstrueres.
- at laboratoriet er underkastet regelmæssigt tilsyn af DANAK.
- at et akkrediteret laboratorium skal have en forsikring, som kan dække laboratoriets ansvar i forbindelse med udførelsen af akkrediterede ydelser.

Prøvningsrapporter, der bærer DANAK's logo, anvendes ved rapportering af akkrediterede ydelser og viser, at disse er foretaget i henhold til akkrediteringsreglerne.

DANAK was established in 1991 in pursuance of the Danish Act No. 394 of 13 June 1990 on the promotion of Trade and Industry.

The requirements to be met by accredited laboratories are laid down in the "Danish Agency for Trade and Industry's" ("Erhvervsfremme Styrelsen's") Statutory Order on accreditation of laboratories to perform testing etc., and GLP-inspection. The Statutory order refers to other documents where the criteria for accreditation are specified further.

The standards DS/EN ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories" and DS/EN 45002 "General criteria for the assessment of testing laboratories" describes fundamental criteria for accreditation. DANAK uses guidance documents to clarify the requirements in the standards, where this is considered to be necessary. These will mainly be drawn up by the "European co-operation for Accreditation (EA)" or the "International Laboratory Accreditation Co-operation (ILAC)" with a view to obtain uniform criteria for accreditation worldwide. In addition, DANAK draws up Technical Regulations with specific requirements for accreditation that are not contained in the standards.

In order for a laboratory to be accredited it is, among other things, required:

- that the laboratory and its personnel are not subject to any commercial, financial and other pressures, which might influence their technical judgement.
- that the laboratory operates a documented quality system.
- that the laboratory has at its disposal all items of equipment, facilities and premises required for correct performance of the service that it is accredited to perform.
- that the laboratory management and personnel have technical competence and practical experience in performing the service that they are accredited to perform.
- that the laboratory has procedures for traceability and uncertainty calculations.
- that accredited testing is performed in accordance with fully validated and documented methods.
- that the laboratory keeps records which contain sufficient information to permit repetition of the test.
- that the laboratory is subject to surveillance by DANAK on a regular basis.
- that the accredited laboratory shall take out an insurance, which covers liability in connection with the performance of accredited services.

Reports carrying DANAK's logo are used when reporting accredited services and show that these have been performed in accordance with the rules of accreditation.



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