Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 02 din 25 august 2023

Solicitantul S.R.L. SC Medica, cu sediul m. Chişinău, str. Alecu Russo 9/3, nr. 143, tel. 067111167, e-mail: scmedica@bk.ru,

solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Utilaj audiologic/ Echipament audiometric, Denumirea comercială: Interacoustics, Producătorul: Interacoustics S/A, Țara: Danemarca, Model Audiometru (Screening audiometer) PA5.

Se anexează următoarele documente:

1. Declarația de conformitate CE emisă de producător pentru dispozitivele medicale fabricate.
2. Certificatul de conformitate CE valabil pentru dispozitivele medicale fabricate.
3. Actul prin care producătorul își desemnează reprezentantul.
4. Declarația pe propria răspundere privind veridicitatea actelor.
5. Lista dispozitivelor medicale prezentate spre notificare în format Excel.

Data 25 august _2023
Directorul S.R.L. SC Medica
Casmînin Serghei

Semnătura _____

Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	Accept
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	Nr. 7226 din 28.08.23
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	Streltov Nicoleta, Birou inregistrare
Semnătura persoanei responsabile	

Interacoustics

EU-MDR Declaration of Conformity

It has been demonstrated that:

Product:

Product name:	PA5
Product type:	Screening Audiometer
Trademark:	Interacoustics
Class.:	IIa
Basic UDI-DI:	5711117_80000352_2B

Manufactured by:

Name:	**Interacoustics A/S**	SRN:	**DK-MF-000001216**
Address:	**Audiometer Allé 1**	Phone No.:	**(+45) 63713555**
Area code/Area:	**5500 Middelfart**	Fax No.:	**(+45) 63713522**
State/Country:	**Denmark**		

Is in conformity with the European Regulation (EU) 2017/745 and Directive 2011/65/EU.

Conformity assessment: Annex IX (Quality system and technical documentation assessment)
MDR-Certificate No.: G10 044841 0027
Valid until: 2026-09-09

Notified Body: TÜV SÜD Product Service GmbH
Ridlerstrasse 65, D-80339 Munich / Germany
ID No.: 0123

This declaration is issued on the sole responsibility of:

Company:	**Interacoustics A/S**
Address:	**Audiometer Allé 1**
Address:	**5500 Middelfart**
State/Country:	**Denmark**

Place: Middelfart

Signature: Erik Nielsen
Name: **Erik Nielsen**
Title: **Director, Regulatory & Compliance**

Date: 2021-10-22 (YYYY-MM-DD)

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

TÜV SÜD 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 044841 0027 Rev. 00

Manufacturer: **Interacoustics A/S**
Audiometer Allé 1
5500 Middelfart
DENMARK

SRN Manufacturer: DK-MF-000001216

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 and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 044841 0027 Rev. 00

Report No.: 713183048

Valid from: 2021-09-10
Valid until: 2026-09-09

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2021-09-10

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BS-MDR-099

TÜV SÜD 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 044841 0027 Rev. 00

Classification:	IIa
Device Group:	Z121401 - AUDIOMETERS Z121403 - EVOKED POTENTIAL AUDIOMETRY INSTRUMENTS Z121404 - VESTIBULAR SYSTEM ANALYSIS INSTRUMENTS Z12149001 - AUDITORY FUNCTION SCREENING DEVICES Z12149004 - CALORIC IRRIGATION UNITS Z12149005 - MIDDLE EAR ANALYSERS
Intended Purpose:	-
The validity of this certificate depends on conditions and/or is limited to the following:	- none -

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Product Service

Confirmation Statement related to the EU Certificate (MDR)

List of Sites involved in the Product Realisation Processes

No. GRS 044841 0029 Rev. 01

Manufacturer:

Interacoustics A/S
Audiometer Allé 1
5500 Middelfart
DENMARK

This List of Sites is only valid in combination with the following EU Certificate (MDR): **G10 044841 0027 Rev. 00**

The following pages list all sites under the manufacturer's quality system where product realisation processes are conducted for those devices covered by the aforementioned EU Certificate pursuant to the Regulation (EU) 2017/745 (MDR) on medical devices.

Report No.: 713297268

Valid until: 2026-09-09

Issue Date: 2023-03-28

M. Häuserer

(Mirjam Häuserer)
PS-MHS-FA-0 – Foreign Affairs

TÜV SÜD Product Service GmbH • Ridlerstraße 65 • 80339 Munich • Germany

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Product Service

Confirmation Statement related to the EU Certificate (MDR)

List of Sites involved in the Product Realisation Processes

No. GRS 044841 0029 Rev. 01

Sites:

Interacoustics A/S
Audiometer Allé 1, 5500 Middelfart, DENMARK

DGS Diagnostics Sp. z o. o.
Rosówek 43, 72-001 Kolbaskowo, POLAND

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Interacoustics

Interacoustics A/S
Audiometer Allé 1
5500 Middelfart
Denmark

T +45 6371 3555
F +45 6371 3522

info@interacoustics.com
interacoustics.com

CVR 1501 5446

Letter of Authorization

We, Interacoustics A/S, based in Denmark, Audiometer Allé 1, DK 5500 Middelfart

assign SC Medica LTD, based in Republic of Moldova, mun. Chisinau, Alecu Russo 9/3, Nr.143,

as **authorized representative** in correspondence with the conditions of directive 93/42/EEC, 98/79/EEC or 90/385/EEC.

We declare that the company mentioned above is authorized to register, notify, renew, or modify the registration of medical devices on the territory of the Republic of Moldova, and to perform Essential Duties required by Law No. 102 09.06.2017 regarding medical devices.

Interacoustics
5500 Middelfart, Denmark
www.interacoustics.com

Place: Middelfart, Denmark

Date: 09.06.2021

Signed: Director Regulatory and Compliance

Erik Nielsen

Erik Nielsen

Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitantul S.R.L. SC Medica, cu sediul m. Chișinău, str. Alecu Russo 9/3, nr. 143, tel. 067111167, e-mail: scmedica@bk.ru,

declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

Utilaj audiologic/ Echipament audiometric, Denumirea comercială: Interacoustics, Producătorul: Interacoustics S/A, Țara: Danemarca, Model Audiometru (Screening audiometer) PA5.

Sunt autentice și corespund realității.

Directorul S.R.L. SC Medica *Semnătura e-sign*
Casmînin Serghei

Data 25 august _2023