



Interacoustics

EC Declaration of Conformity

It has been demonstrated that:

Product:

Product type: Impedance Audiometer

Class: IIa

Trademark: Interacoustics

Type No.: MT10

Manufactured by:

Name: Interacoustics A/S

Address: Audiometer Allé 1

Area code/Area: 5500 Middelfart

Phone No.: (+45) 63713555

Country: Denmark

Fax No.: (+45) 63713522

Is in conformity with the following Directives of the European Parliament and of the Council:

- 93/42/EEC of 14 June 1993, including all amendments, concerning medical devices, fulfilling the essential requirements in appendix I through application of a full quality system according to appendix II.3
- 2011/65/EU of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

The conformity is achieved by the fulfilling of the following main standards:

- IEC 60601-1:2012 General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 Electromagnetic disturbances – Requirements and tests

Valid until: 2023-09-30

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

This declaration is made on the sole responsibility of:

Company: Interacoustics A/S

Address: Audiometer Allé 1

Address: 5500 Middelfart

Phone No.: (+45) 63713555

Country: Denmark

Fax No.: (+45) 63713522

Signature:

Name:

Title:

Erik Nielsen

Erik Nielsen

Director, Regulatory & Compliance

Date:

2019-11-25

(YYYY-MM-DD)


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