



## EU-Konformitätserklärung EU Declaration of Conformity

Sennheiser electronic GmbH & Co. KG  
Am Labor 1  
D-30900 Wedemark, Germany

declares under the sole responsibility that the product:

Model:                   Audiology Dynamic Headphone  
Model No:               HDA 300

with the included components

Devices:                 HZH 350

are in conformity with the provisions of the following relevant harmonized legislations of the European Union.

**Quality Assurance:** ISO 9001

Wedemark, 16.10.2020

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Dr. Andreas Sennheiser  
CEO

The history of this document is listed on the last page

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Amtsgericht Hannover HRA 120100  
phG: Sennheiser Beteiligungs-GmbH

Sitz 30900 Wedemark,  
Amtsgericht Hannover HRB 120179

### Applied directives and standards:

<b>The device 'HDA 300' comply with the following:</b>			
<b>Position</b>	<b>Name</b>	<b>Description</b>	<b>Version</b>
1020	93/42/EEC	MDD Council Directive 93/42/EEC of 14 June 1993	1993-06
1050	EN 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2009 + AC:2010
1055	EN 10993-3	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	2014
1065	EN 10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	2013
1090	EN 15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	2016
3600	EN 60601-1	Medical electrical equipment - Part 1 General requirements for basic safety and essential performance	2006 + AC:2010 +A1:2013
3650	EN 60645-1	Electroacoustics - Audiological equipment - Part 1: Pure-tone audiometers	2017
7801	2011/65/EU	RoHS Directive 2011/65/EU Restriction of the use of certain hazardous substances (publication references OJ L 174, 01.07.2011, p.88-110) amended by (EU) 2015/863)	2011-06 with all amendments
7820	EN IEC 63000	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances	2018-12

### Document History

Revision Date:	Revision Description	Remarks
2013-05-07	First version	
2018-10-02	Second version	
2020-01-22	Third version	Standards updated
2020-10-16	Accessory update, standards update	