



EU-Konformitätserklärung EU Declaration of Conformity

Sennheiser electronic GmbH & Co. KG
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erklärt in alleiniger Verantwortung, dass das Produkt:
declares under the sole responsibility that the product:

Model: Audiology Dynamic Headphone
Model No: HDA 300

und alle im Anhang aufgeführten Varianten mit den Bestimmungen der nachstehenden EU-Richtlinie(n)
(einschließlich aller zutreffenden Änderungen) übereinstimmen; und unter Anwendung der harmonisierten
Normen entwickelt, konstruiert und gefertigt worden sind.

and all variations specified in the annex are in conformity with the provisions of the following EU directive(s)
(including all applicable amendments); and are designed and manufactured with application of the
harmonized standards.

Qualitätszusicherung: Der Herstellerbetrieb ist nach ISO 9001 zertifiziert

Quality Assurance: The manufacturing organisation is certified according to ISO 9001

CE was at first applied: 2013-05-07

Die Historie dieses Dokuments befindet sich auf der letzten Seite
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Applied directives and standards:

The device 'HDA 300' comply with the following:			
Position	Name	Description	Version
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 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	2009
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	2001
7800	2011/65/EU	RoHS Directive 2011/65/EU Restriction of the use of certain hazardous substance	2011-07
7810	EN 50581	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances	2012-09

Document History

Revision Date:	Revision Description	Remarks
2013-05-07	First version	
2018-10-02	Second version	