Audio Service
hear · understand · communicate

EC DECLARATION OF CONFORMITY

according to:

MDD Council Directive 93/42/EEC for medical products, Annex II (without chapter II.4)
ROHS Council Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment
RED Council Directive 2014/53/EU on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC

Manufacturer:	**AS AUDIO-SERVICE GmbH**
Street:	**Alter Postweg 190**
City:	**32584 Löhne**
Country	**Deutschland / Germany**

Herewith we declare under our sole responsibility that the following medical devices:

In-The-Ear (ITE) Hearing Aids	**Rule 9, Class II a**
Behind-The-Ear (BTE) Hearing Aids	**Rule 9, Class II a**
Ear Inserts (Earmoulds)	**Rule 5, Class II a**
Accessories	**Rule 5, Class II a**

for the products listed as follows:

Attachment 1	product range:	standard portfolio	Version 58 (effective 2019.01.21)
Attachment 2	product range:	export markets	Version 18 (effective 2018.07.13)

complies with the essential requirements and applicable standards as follows:

MDD	DIN EN 60118-0:2016, DIN EN 60118-7:2006, DIN EN 60118-13:2013, EN ISO 13485:2012, DIN EN ISO 10993-1:2010, DIN EN ISO 10993-5:2009, DIN EN ISO 10993-10:2014, DIN EN ISO 15223-1:2017, DIN EN ISO 14971:2013, DIN EN 60601-1:2013, DIN EN 60601-2-66:2015, DIN EN 62304:2016
RoHS	EN 50581:2012
RED	EN 300 330 V2.1.1, EN 300 328 V2.1.1 (*with bluetooth), EN 301 489-17 V2.2.1
Notified Body	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany Identification no.: 0123

Place and valid from date: Löhne, 2019-01-21

(Thomas Mettang)
Managing Director (CEO)

Florian Häusler
(Florian Häusler)
Quality Management

This declaration will be renewed on any significant change of product, product range, standards and laws.