

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 59 (effective 2019.05.24)
Attachment 2	product range: export markets	Version 19 (effective 2019.05.24)

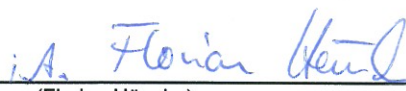
complies with the essential requirements and applicable standards as follows:

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, 2019-05-24



 (Thomas Mettang)
 Managing Director (CEO)



 (Florian Häusler)
 Quality Management

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