

Declaration of Conformity

Valid from: 21.02.2017
Valid until: 20.02.2022

Manufacturer: audifon GmbH & Co. KG
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Products / accessories:

Device name	Item number	Date of first CE marking
vico M	019885	18.10.2012
vico M TRT	019886	18.10.2012
vico S	019883	18.10.2012
vico S TRT	019884	18.10.2012
vico XS	021221	26.09.2013
vico XS TRT	021222	26.09.2013
vico S+	021223	26.09.2013
vico S+ TRT	021224	26.09.2013
vico P	021690	14.03.2014
vico P TRT	021691	14.03.2014
miro XS	021340	28.10.2013
miro XS TRT	021341	28.10.2013
miro S+	021337	28.10.2013
miro S+ TRT	021338	28.10.2013
miro P	021701	14.03.2014
miro P TRT	021702	14.03.2014
miro R HE S	021770, 021957	14.03.2014
miro R TRT HE S	021771, 021957	14.03.2014
miro R HE M	021770, 021958	14.03.2014
miro R TRT HE M	021771, 021958	14.03.2014
libra XS	021141	26.09.2013
libra XS TRT	021142	26.09.2013
libra S+	021136	26.09.2013
libra S+ TRT	021137	26.09.2013
libra P	021679	14.03.2014
libra P TRT	021680	14.03.2014
libra R HE S	021757, 021957	14.03.2014
libra R HE S TRT	021758, 021957	14.03.2014
libra R HE M	021757, 021958	14.03.2014
libra R HE M TRT	021758, 021958	14.03.2014
saga R HE S	022233, 021957	22.07.2014
saga R TRT HE S	022234, 021957	22.07.2014
saga R HE M	022233, 021958	22.07.2014
saga R TRT HE M	022234, 021958	22.07.2014
saga XS	022218	22.07.2014
saga S+	022208	22.07.2014

Device name	Item number	Date of first CE marking
saga S+ TRT	022209	22.07.2014
saga P	022223	22.07.2014
saga P TRT	022224	22.07.2014

Part 1:

We declare under our sole responsibility that the above-mentioned products comply with the following directives:

Medical Device Directive (MDD) 93/42 EEC, appendix I
Medical Device Directive 2007/47/EEC

The above-mentioned hearing aids are classified in the category IIa and they are marked with

CE 0297

Our company is certified according to DIN EN ISO 13485 and fulfils the relevant directives 93/42/EWG, appendix II part 3.

The conformity of the Medical Device Directive is certified by DQS Medizinprodukte GmbH (NB 0297).

DQS Medizinprodukte GmbH
August Schanz Straße 21
60433 Frankfurt am Main

Part 2:

We declare under our sole responsibility that the above-mentioned products / accessories comply with the following directives:

RoHS Directive 2011/65/EG

Kölleda, 16.02.2017



Ingo Henze
Qualitymanager