

EC DECLARATION OF CONFORMITY

Manufacturer **Sivantos GmbH**
Henri-Dunant-Strasse 100
91058 Erlangen
Germany

Brand: **Siemens**
Series: **Insio**
Type of Device: **Hearing Aids**
Product Identification: **Custom hearing aids**
 Insio 3mi custom Insio 3bx custom
 Insio 5mi custom Insio 5bx custom
 Insio 7mi custom Insio 7bx custom

We declare under our sole responsibility that above products are in conformity with the following Directives:

Council Directive 93/42/EEC as amended by Dir. 2007/47/EC (MDD)

Conformity assessment procedure: **Annex II without chapter II.4 of 93/42/EEC**
Notified Body: **TÜV SÜD Product Service GmbH, Notified Body No.: NB 0123
Ridlerstr. 65, 80339 München, Germany**
Classification of device: **Class IIa** (according to Annex IX to Council Directive 93/42/EEC)
The products meet the applicable standards and the basic requirements of the Directive 93/42/EEC Annex I.

Council Directive 2011/65/EU (RoHS)

Relevant Harmonized Standards: **EN 50581:2012**

Council Directive 2014/53/EU (RED)

Applied standards: **EN 300 330 V2.1.1**
(without Bluetooth interface)
The products are in compliance with the essential requirement of the directive.

Place and valid from date **Erlangen, June 13th, 2017**

Name Günther Pausch
(Managing Director)

i.V. Rainer Walther
(Quality Management)

Signature 



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