

EC DECLARATION OF CONFORMITY

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

Brand: **SAT**
Co-Brand: Specsavers
Series: Specsavers
Type of Device: Hearing Aids
Product Identification: See next page

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.

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Product Identification – Standard hearing aids:

Advance miniRIC 816	Advance miniRIC 416	Advance miniRIC 316	
Advance Open 316	Advance Open 216 ¹	Advance Open 116 ¹	
Advance OTE 816	Advance OTE 616	Advance OTE 416	
Advance OTE 316	Advance OTE 216 ¹		
Advance RIC 816	Advance RIC 416	Advance RIC 316	
Advance RIC+ 816	Advance RIC+ 416	Advance RIC+ 316	
Advance P 816	Advance P 616	Advance P 416	
Advance P 316	Advance P 216 ¹		
Advance miniRIC 817	Advance miniRIC 617	Advance miniRIC 417	
Advance OTE 817	Advance OTE 617	Advance OTE 417	
Advance Open 417			
Advance RIC 817	Advance RIC 617	Advance RIC 417	
Advance RIC+ 817	Advance RIC+ 617	Advance RIC+ 417	
Advance P 817	Advance P 617	Advance P 417	
Advance SP 817	Advance SP 617	Advance SP 417	Advance SP 317

Product Identification – Custom hearing aids:

Advance 816 custom	Advance 616 custom	Advance 416 custom
Advance 316 custom	Advance 216 custom ¹	
Advance custom 817	Advance custom 617	Advance custom 417

¹: no wireless technology