

EC DECLARATION OF CONFORMITY

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

Brand: **Siemens**
 Series: **Intuis**
 Type of Device: **Hearing Aids**

Product Identification – BTE (Behind The Ear) hearing aid:

Intuis DIR	Intuis DIR SOX	Intuis Life	Intuis S DIR	Intuis SP DIR
Intuis SP SOX				
Intuis Pro DIR	Intuis Pro S DIR	Intuis Pro SP DIR		
Intuis 2 M	Intuis 2 P	Intuis 2 S	Intuis 2 SP	

Product Identification – Custom hearing aids:

Intuis CIC	Intuis HS	Intuis ITC	Intuis ITE	Intuis MC
Intuis 2 custom	Intuis 2 Click CIC	Intuis 2 Click ITC		

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

Council Directive 93/42/EEC (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

Place and valid from date Erlangen, September 26th, 2016

Name i.V. Josef Feldmeier i.V. Rainer Walther
 (Research & Development) (Quality Management)

Signature Josef Feld Rainer Walther

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