

# EC DECLARATION OF CONFORMITY

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

Brand: **Siemens**

Series: Nitro

Type of Device: Hearing Aids

Product Identification: BTE (Behind The Ear) hearing aid

Nitro 301 SP Nitro 701 SP

Nitro 3mi Nitro 7mi

Product Identification: Custom hearing aids

Nitro 3mi custom Nitro 7mi 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 13<sup>th</sup>, 2017

Name Günther Pausch i.V. Rainer Walther  
(Managing Director) (Quality Management)

Signature  

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