

EC DECLARATION OF CONFORMITY

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

Brand: **Siemens**

Series: Orion

Type of Device: Hearing Aids

Product Identification: RIC (Receiver In the Canal) hearing aid
 Orion RIC Orion 2 RIC 312 Orion 2 RIC 10

Product Identification: BTE (Behind The Ear) hearing aid
 Orion M Orion P Orion S Orion SP
 Orion 2 M Orion 2 P Orion 2 S

Product Identification: Custom hearing aids
 Orion custom Orion 2 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 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.