

EC DECLARATION OF CONFORMITY

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

Brand: **Rexton**

Series: **Insite**

Type of Device: **Hearing Aids**

Product Identification: **BTE (Behind The Ear) hearing aid**
Insite+ Free
Insite+ P

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.