

EC DECLARATION OF CONFORMITY

Manufacturer

Sivantos GmbH
Henri-Dunant-Strasse 100
91058 Erlangen
Germany

Brand:

Rexton

Series:

Day

Type of Device:

Hearing Aids

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

Day 4+ Free *	Day 4+ HP *	Day 4+ Open *	Day 4+ P *	Day 4+ P (NR) *
* This product has no wireless function. RED Directive is not applicable.				
Day 6+ Free	Day 6+ HP	Day 6+ Open	Day 6+ P	Day P (NR)

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.