

# EC DECLARATION OF CONFORMITY

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

Brand: **Rexton**  
Series: **Onyx**  
Type of Device: **Hearing Aids**

Product Identification – RIC (Receiver In the Canal) hearing aid:

Onyx 12+	
Onyx 8+	Onyx 8+ NR
Onyx Eco+	Onyx Eco+ NR

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.

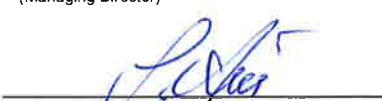
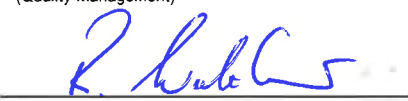
**Council Directive 2011/65/EU (RoHS)**

Relevant Harmonized Standards: **EN 50581:2012**

**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	<u>Günther Pausch</u> (Managing Director)	<u>i.V. Rainer Walther</u> (Quality Management)
Signature		

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