

EC DECLARATION OF CONFORMITY

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

Brand: **Rexton**
Series: **Kirkland**
Type of Device: **Hearing Aids**
Product Identification: **See next page**

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)

¹ Applied standards:
(with Bluetooth interface) **EN 300 328 V2.1.1
EN 300330 V2.1.1**

² Applied Standards
(with Telecoil) **EN 300 422-4 V2.1.1**

³ Applied Standards
(with Wireless Function) **EN 300330 V2.1.1**

The products are in compliance with the essential requirement of the directive.

Directive 2014/30/EU (EMC) harmonized standards

⁴ Applied standards:
(with Bluetooth interface) **EN 301489-1 V1.9.2**

Place and valid from date **Erlangen, April 6th, 2018**

Name **Christian Honsig**
(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.

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Product Identification – Standard hearing aid:

KS 7.0 ^{1/2/3/4}	KS 7.0 NR ^{1/2/3/4}	
KS 8.0 ^{1/3/4}	KS 8.0 T ^{1/2/3/4}	KS 8.0 DEMO ^{1/3/4}
KS HA04 ^{1/2/4}	KS HA04 NR ^{1/2/4}	
Trax 42 ^{1/2/4}	Trax 42 NR ^{1/2/4}	
Trax 42 XM ^{1/2/4}	Trax 42 XM NR ^{1/2/4}	
Trax 42 XS ^{1/4}		
Trax 42 MB ^{1/2/4}	Trax 42 MB NR ^{1/2/4}	
Trax 42 PB ^{1/2/4}		
Quintra ^{1/4}	Quintra NR ^{1/4}	
Legato MB ^{1/2/4}	Legato MB NR ^{1/2/4}	
Legato IX ^{1/4}		
Legato LI ^{1/2/3/4}		
Legato PB ^{1/2/3/4}		
Adore MB ^{1/2/3/4}		

Product Identification – Custom hearing aid:

Trax 42 custom ^{1/2/4}
Legato custom ^{1/2/4}