sivantos

# EC DECLARATION OF CONFORMITY

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| Manufacturer | **Sivantos GmbH**<br>Henri-Dunant-Strasse 100<br>91058 Erlangen<br>Germany |
| Brand: | **Siemens** |
| Series: | PURE |
| Type of Device: | Hearing Aids |
| Product Identification: | RIC (Receiver In the Canal) hearing aid |

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| Ear Q P 3mi | Pure 101 XCL+*<br>** This product has no wireless function. RED Directive is not applicable.* | |
| Pure Carat 301 XCL | Pure Carat 501 XCL | Pure Carat 701 XCL |
| Pure Carat 301 XCL+ | Pure Carat 501 XCL+ | Pure Carat 701 XCL+ |
| Pure 3mi | Pure 5mi | Pure 7mi |
| Pure+ 3mi | Pure+ 5mi | Pure+ 7mi |
| Pure 3bx | Pure 5bx | Pure 7bx |
| Pure+ 3bx | Pure+ 5bx | Pure+ 7bx |

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)**

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| 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<br>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)**

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| Relevant Harmonized Standards: | EN 50581:2012 |

**Council Directive 2014/53/EU (RED)**

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| Applied standards:<br>(without Bluetooth interface) | EN 300 330 V2.1.1 |

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

Place and valid from date Erlangen, June 13th, 2017

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| Name | Günther Pausch<br>(Managing Director) | i.V. Rainer Walther<br>(Quality Management) |
| Signature |  |  |

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