

Sivantos GmbH · Henri-Dunant-Strasse 100 · D-91058 Erlangen

Federal Communication Commission
Equipment Authorization Division, Application
Processing Branch
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Date February 20th, 2018

Subject: **Limited Modular Approval Statement**
FCC Certification Number: SGI-MIM001
Model Name/Number: e2e 3.5

TO WHOM IT MAY CONCERN

Pursuant to Paragraph CFR § 15.212, we herewith declare for our module:

Modular approval requirement	Yes	No *
(a) The radio elements must have the radio frequency circuitry be shielded. Physical/discrete and tuning capacitors may be located external to the shield, but must be on the module assembly.		x
<p>*Please provide a detailed explanation if the answer is "No.": The model above referred does not have its own RF shielding. This limitation is one of the reasons why Sivantos requests only the Limited Modular Approval. The module is to be used exclusively by Sivantos or by its affiliates or to be sold to Original Equipment Manufacturers (OEM), integrated under controlled conditions and always assuring the total emission and immunity are within specifications. The module is a fully integrated radio module for short range wireless data exchange, including radio circuitry on board and is intended for Sivantos and affiliates wireless hearing aids only. Therefore, the module cannot be used directly by end users. The behavior of the wireless module is locked by design and can only be changed by Sivantos or its affiliates, so the compliance of the end product is always ensured.</p>		
(b) The module shall have buffered modulation/data input(s) (if such inputs are provided) to ensure that the module will comply with the requirements set out in the applicable RSS standard under conditions of excessive data rates or over-modulation.	x	
<p>*Please provide a detailed explanation if the answer is "No.":</p>		

(c) The module shall have its own power supply regulation on the module. This is to ensure that the module will comply with the requirements set out in the applicable standard regardless of the design of the power supplying circuitry in the host device which houses the module.		x
<p>*Please provide a detailed explanation if the answer is "No.": The wireless parts of the radio module share the power supply with other digital parts, like Digital ASIC. As producer and integrator of the radio module, it is assured that the power supplied will not affect its correct functioning. We apply for a Limited Modular Approval also due to this constraint.</p>		
(d) The module shall comply with the provisions for external power amplifiers and antennas detailed in this standard. The equipment certification submission shall contain a detailed description of the configuration of all antennas that will be used with the module.	x	
<p>*Please provide a detailed explanation if the answer is "No.":</p>		
(e) The module shall be tested for compliance with the applicable standard in a stand-alone configuration, i.e. the module must not be inside another device during testing.		x
<p>*Please provide a detailed explanation if the answer is "No.": The modular transmitter has been tested integrated on a typical host, a hearing aid instrument that best represents all the future hosts where the module will be used by Sivantos. Due to the size limitations of the hearing aids instruments, the radio module is in the same PCB of the host making impossible to test it on a standalone configuration. Please refer to the test reports in this filing for details on the module radio performance when integrated in the representative host.</p>		
(f) The module shall comply with the Category I equipment labeling requirements and CFR § 15.212(a)(1)(vi).		x
<p>*Please provide a detailed explanation if the answer is "No.": The size of the module is too small for the regulatory FCC label in its short form to be placed on the side of the plastic shell holding it, which is therefore displayed in the user manual. Response to a inquiry was received from FCC OET Inquiry staff (tracking number 560209). Please find the eMail and rationale how we follow the advise for Nx platform in separate document in this filing.</p>		
(g) The module shall comply with applicable FCC RF exposure requirement which are based on the intended use/configurations.	x	
<p>*Please provide a detailed explanation if the answer is "No.":</p>		
(h) The modular transmitter complies with all applicable FCC rules. Instructions for maintaining compliance are given in the user instructions.	x	
<p>*Please provide a detailed explanation if the answer is "No.":</p>		

With kind regards,

Richard Rose

Richard Rose

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