

## RF Exposure Report

**Report No.:** SABHSI-WTW-P21080133

**FCC ID:** 2AYGR-3042

**Test Model:** CLS121 (Marvin IPG)

**Received Date:** Aug. 04, 2021

**Test Date:** Aug. 26 ~ Sep. 03, 2021

**Issued Date:** Feb. 18, 2022

**Applicant:** Saluda Medical Pty Ltd

**Address:** Ground Floor, 407 Pacific Highway Artarmon, NSW, 2064, Australia

**Issued By:** Bureau Veritas Consumer Products Services (H.K.) Ltd., Taoyuan Branch  
Lin Kou Laboratories

**Lab Address:** No. 47-2, 14th Ling, Chia Pau Vil., Lin Kou Dist., New Taipei City, Taiwan

**Test Location:** No. 19, Hwa Ya 2nd Rd., Wen Hwa Vil., Kwei Shan Dist., Taoyuan City  
33383, Taiwan

**FCC Registration /** 788550 / TW0003  
**Designation Number:**



This report is for your exclusive use. Any copying or replication of this report to or for any other person or entity, or use of our name or trademark, is permitted only with our prior written permission. This report sets forth our findings solely with respect to the test samples identified herein. The results set forth in this report are not indicative or representative of the quality or characteristics of the lot from which a test sample was taken or any similar or identical product unless specifically and expressly noted. Our report includes all of the tests requested by you and the results thereof based upon the information that you provided to us. You have 60 days from date of issuance of this report to notify us of any material error or omission caused by our negligence, provided, however, that such notice shall be in writing and shall specifically address the issue you wish to raise. A failure to raise such issue within the prescribed time shall constitute your unqualified acceptance of the completeness of this report, the tests conducted and the correctness of the report contents. Unless specific mention, the uncertainty of measurement has been explicitly taken into account to declare the compliance or non-compliance to the specification.

## Table of Contents

Release Control Record .....	3
1 Certificate of Conformity .....	4
2 Evaluation Limit.....	5
3 SAR Test Exclusion Thresholds.....	6
4 Conclusion .....	6

### Release Control Record

Issue No.	Description	Date Issued
SABHSI-WTW-P21080133	Original release	Feb. 18, 2022

## 1 Certificate of Conformity

**Product:** Evoke™ Closed Loop Stimulator

**Brand:** Saluda Medical

**Test Model:** CLS121 (Marvin IPG)

**Sample Status:** Engineering sample

**Applicant:** Saluda Medical Pty Ltd

**Test Date:** Aug. 26 ~ Sep. 03, 2021

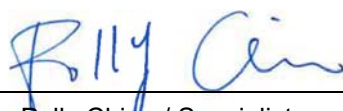
**Standards:** FCC Part 2 (Section 2.1093)

**References Test** Part 1.1307 (b)(3)(i)(A)

**Guidance:** KDB 447498 D01 General RF Exposure Guidance v06

The above equipment has been tested by **Bureau Veritas Consumer Products Services (H.K.) Ltd., Taoyuan Branch**, and found compliance with the requirement of the above standards. The test record, data evaluation & Equipment Under Test (EUT) configurations represented herein are true and accurate accounts of the measurements of the sample's RF characteristics under the conditions specified in this report.

**Prepared by :**



Polly Chien / Specialist

**Date:**

Feb. 18, 2022

**Approved by :**



Jeremy Lin / Project Engineer

**Date:**

Feb. 18, 2022

## 2 Evaluation Limit

According to Part 1.1307(b)(3)(i)(A) &(b)(3)(ii)(A)

The available maximum time-averaged power is no more than 1 mW, regardless of separation distance. This exemption may not be used in conjunction with other exemption criteria other than those in paragraph (b)(3)(ii)(A) of this section. Medical implant devices may only use this exemption and that in paragraph (b)(3)(ii)(A)

The available maximum time-averaged power of each source is no more than 1 mW and there is a separation distance of two centimeters between any portion of a radiating structure operating and the nearest portion of any other radiating structure in the same device, except if the sum of multiple sources is less than 1 mW during the time-averaging period, in which case they may be treated as a single source (separation is not required). This exemption may not be used in conjunction with other exemption criteria other than those is paragraph (b)(3)(i)(A) of this section. Medical implant devices may only use this exemption and that in paragraph (b)(3)(i)(A).

Also, according to KDB 447498 D01 General RF Exposure Guidance v06 clause 4.2.4

For Transmitters implanted in the body of a user, below requirement shall be met.

When the aggregate of the maximum power available at the antenna port and radiating structures of an implanted transmitter, under all operating circumstances, is  $\leq 1.0$  mW, SAR test exclusion may be applied. The maximum available output power requirement and worst case operating conditions must be supported by power measurement results, based on device design and implementation requirements, and fully justified in a SAR analysis report according to KDB Publication 865664 D02, in lieu of SAR measurement or numerical simulation.

### 3 SAR Test Exclusion Thresholds

Maximum tune-up transmitter power:

Frequency (MHz)	EIRP (dBm)	EIRP (mW)	Antenna Gain (dBi)	Conducted Power (dBm)	Conducted Power (mW)	Limit (mW)	Result
402 - 405	-33.5	0.0004	-30	-3.50	0.447	1	Pass

Note:

1. The above EIRP Power is Tune-up Power which client declared.
2. Max. Power (dBm) = EIRP (dBm) – antenna gain (dBi) = -33.50 – (-30) = -3.50
3. Determining compliance based on the results of the compliance measurement, not taking into account measurement instrumentation uncertainty.

### 4 Conclusion

Since Source-base time average power is below maximum time-averaged power 1 mW, the SAR evaluation is not required.

---END---