

# **Test report**

N°: 131328-664446HCr2015-08-04

**Subject** 

Radio spectrum Matters (ERM) tests according to standards:

47 CFR Part 95I & RSS-243 & RSS-Gen, Issue 4

Issued to

SORIN

Parc d'Affaires NOVEOS

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Apparatus under test

♥ Product

Platinium implantable cardioverter defibrillator

Trade mark

SORIN Group

Manufacturer

Sorin CRM S.r.I — Italy

♥ Model

Son RCRT - D 1841

Serial number

126DD007

♥ FCC ID

YSGCRTDSOR1841

**♥ IC ID** 

10270A-CRTDSOR1841

6230B

**Test date** 

2014/10/03 to 2014/10/07 & 2015/01/14 & 2015/01/15

**Test location** 

Ecuelles Fontenay Aux Roses

Test performed by

Laurent DENEUX & Mathieu CERISIER

Composition of document

41 pages

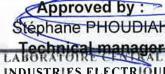
Modification of the last version

2015/08/04

Document issued on

2015/02/10

Written by: Laurent DENEUX & Mathieu CERISIER **Tests operator** 





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# SUMMARY

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| 1  | TEST | Pp | ACD. | ۸М   |
|----|------|----|------|------|
| 1. | IESI | FK | UGR  | AIVI |

References

Standards: -47 CFR FCC Part 95I

-RSS-243 -RSS-Gen -FCC 15.207 -FCC 15.109

#### Requirements:

| Nequirements.  | 1   |
|--|---|
| Clause (FCC Part 95I) Test Description                                       | TEST RESULT - Comments  |
| FCC § 95.627(e) & RSS-243 § 5.3 – Frequency error                            | ⊠PASS □FAIL □NA □NP (Limited Program)   |
| FCC § 95.633(e) & RSS-243 § 5.1 – Emission bandwidth                         | ⊠PASS □FAIL □NA □NP (Limited Program)   |
| RSS-Gen § 6.6 – Occupied bandwidth   | ⊠PASS □FAIL □NA □NP (Limited Program)   |
| FCC § 95.639(f) & RSS-243 § 5.4 – Transmitter output power                   | ⊠PASS □FAIL □NA □NP (Limited Program)   |
| FCC § 15.207(d) & RSS-Gen § 8.8 – AC conducted emissions                     | □PASS □FAIL ⊠NA □NP (Limited Program)   |
| FCC § 95.635(d) & RSS-243 § 5.5 – Transmitter unwanted emission              | ⊠PASS □FAIL □NA □NP (Limited Program)   |
| FCC 15.109 & RSS-243 § 5.6 – Receiver spurious emissions                     | ⊠PASS □FAIL □NA □NP (Limited Program)   |
| FCC 95.627 (a)(3) & RSS-243 § 5.7.1 – LBT threshold power level              | □PASS □FAIL ☑NA (MICS Communication session initiated by ULP-AMI-P only) □NP (Limited Program)  |
| FCC 95.627 (a)(1) & RSS-243 § 5.7.2 – Monitoring system bandwidth            | □PASS □FAIL ☑NA (MICS Communication session initiated by ULP-AMI-P only) □NP (Limited Program)  |
| FCC 95.627 (a)(2) & RSS-243 § 5.7.3 –Monitoring system scan cycle time       | □PASS □FAIL ☑NA (MICS Communication session initiated by ULP-AMI-P only) □NP (Limited Program)) |
| FCC 95.627 (a)(2) & RSS-243 § 5.7.4 –Minimum channel monitoring period       | □PASS □FAIL ☑NA (MICS Communication session initiated by ULP-AMI-P only) □NP (Limited Program)  |
| FCC 95.627 (a)(4) & RSS-243 § 5.7.5 – Channel access                         | □PASS □FAIL ☑NA (MICS Communication session initiated by ULP-AMI-P only) □NP (Limited Program)  |
| FCC 95.627 (a)(4) & RSS-243 § 5.7.6 – Discontinuation of MICS session        | □PASS □FAIL ☑NA (MICS Communication session initiated by ULP-AMI-P only) □NP (Limited Program)  |
| FCC 95.627 (a)(5) & RSS-243 § 5.7.7 – Use of pre-scanned alternative channel | □PASS □FAIL ☑NA (MICS Communication session initiated by ULP-AMI-P only) □NP (Limited Program)  |
| SAR Evaluation   | ⊠PASS □FAIL □NA   |
| This table is a summary of test report, see conclusion of each clause        | of this test report for detail.   |

The product SORIN Group Son RCRT - D 1841, SN: 126DD007 is Compliant according to FCC part 95I & RSS-243 & RSS-Gen standards.

PASS: EUT complies with standard's requirement FAIL: EUT does not comply with standard's requirement

NA: Not Applicable NP: Not Performed



# 2. EQUIPMENT DESCRIPTION

#### 2.1. GENERAL DESCRIPTION

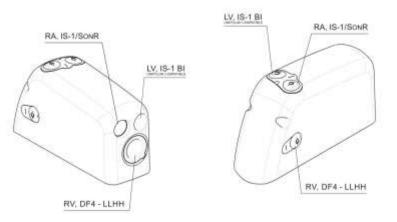
The SORIN Group PLATINIUM SonR CRT D-1841 is an implantable cardioverter defibrillator for the recognition and treatment of ventricular tachycardia and fibrillation, with ventricular resynchronization, in patients with spontaneous or inducible tachyarrhythmias. PLATINIUM SonR CRT-D is equipped with an accelerometer to allow adaptation of pacing to suit the patient's activity.

# 2.2. HARDWARE & SOFTWARE IDENTIFICATION DECLARED BY THE MANUFACTURER

# **Equipment under test (EUT):**



# Leads connection - 1841 model



Photograph of EUT



# • Auxiliary equipment (AE) used for testing: -Inductive Head -Personal Computer





| • | ln | рι | ıt/ | o | ut | pu | t: |
|---|----|----|-----|---|----|----|----|
|   |    |    |     |   |    |    |    |

- none

| •    | <u>Softw</u> | are  | <u>iden</u> | tifica | tion: |
|------|--------------|------|-------------|--------|-------|
| -Sof | tware        | vers | sion:       | ROM    | V2    |

#### **Equipment information:** - Modulation: 2FSK - Transmit operating mode: Multiples antenna Single antenna - Number of transmit chains: $\boxtimes$ 1 □ 2 $\boxtimes$ 1 □ 2 - Number of receiver chains: - Antenna type: External ☐ Plug-in radio device ☐ Combined equipment - Type of the equipment: □ -20°C ☐ 0°C - Temperature range: Tmin: Tnom: Tmax: ☐ 55°C - Test source voltage: Vmin: ☐ 207V/50Hz ☐ 2.5Vdc ☐ 230V/50Hz 🗵 2.62Vdc Vnom: ☐ 253V/50Hz 🗵 3.24Vdc Vmax: ☐ Internal power supply - Type of power source: □ Battery (Lithium-Ion) □ External power supply ☐ Car Charger - Test sequence/test software used: See 2.2. Running Mode - Duty Cycle: □ Continuous duty ☐ Intermittent duty ☐ Continuous operation Representative production model Pre-production model - Equipment type:



- Operating frequency range:

| Frequency            | Band (MHz)  |
|----------------------|-------------|
| 2400MHz to 2483,5MHz | $\boxtimes$ |
| 5150MHz to 5350MHz   |             |
| 5470MHz to 5725MHz   |             |
| 402MHz to 405MHz     | $\boxtimes$ |

-Channel plan:

| Channel | Frequency (MHz) |
|---------|-----------------|
| Cmin: 0 | 402.15          |
| 1       | 402.45          |
| 2       | 402.75          |
| 3       | 403.05          |
| 4       | 403.35          |
| Cnom:5  | 403.65          |
| 6       | 403.95          |
| 7       | 404.25          |
| 8       | 404.55          |
| Cmax: 9 | 404.85          |



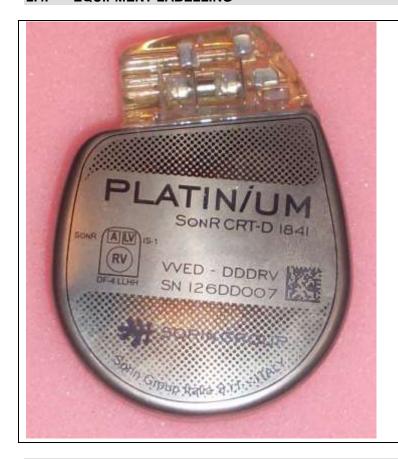
# 2.3. RUNNING MODE

The EUT is set in the following modes during tests:

- Permanent emission with modulation on a fixed channel at the highest power
- Permanent emission without modulation on a fixed channel at the highest power
- Permanent reception

Following commands with the specific test software are used to set the product: See MISC2723A document

# 2.4. EQUIPMENT LABELLING



# 2.5. EQUIPMENT MODIFICATION

| $\boxtimes$   | IJ | Vο | equipment | t modification | has | been | necessary | during | testing. |
|---------------|----|----|-----------|----------------|-----|------|-----------|--------|----------|
| $\overline{}$ | ٦. |    | 11.61     |                |     |      |           |        |          |

☐ Modification applied for following tests:



# 3. FREQUENCY ERROR

# 3.1. TEST CONDITIONS

Test performed by : Mathieu CERISIER

Date of test : 2015/01/14

Ambient temperature : 25°C

Relative humidity : 29%

#### 3.2. TEST SETUP

|   | TI  | <br>4 |        | T 1  | • - | installe |     |
|---|-----|-------|--------|------|-----|----------|-----|
| _ | Ine | ment  | IInaer | IACT | ıc  | Ingralle | ъn. |
|   |     |       |        |      |     |          |     |

In the climatic chamber

On a table

In an anechoic chamber

-Measurement is performed with a spectrum analyzer

☐ On the EUT conducted access

The spectrum analyzer counter and marker peak functions are used to find the frequency error. Detector peak



Photograph for Frequency Error





Photograph for Frequency Error

# 3.3. LIMIT

Frequency error for equipment operating in the 402 MHz to 405 MHz band shall not exceed  $\pm 100$  ppm under normal, extreme or any intermediate set of conditions.

# 3.4. TEST EQUIPMENT LIST

| DESCRIPTION        | MANUFACTURER    | MODEL  | N° LCIE  | Cal_Date                               | Cal_Due                                |
|--------------------|-----------------|--------|----------|--|--|
| Climatic Chamber   | SECASI          | SLT34  | D1024029 | Verified with<br>Temperature<br>Sensor | Verified with<br>Temperature<br>Sensor |
| EMI receiver       | ROHDE & SCHWARZ | ESI40  | A2642010 | 2014/02                                | 2015/02                                |
| Temperature Sensor | AOIP            | TM6630 | B4041042 | 2014/12                                | 2015/12                                |

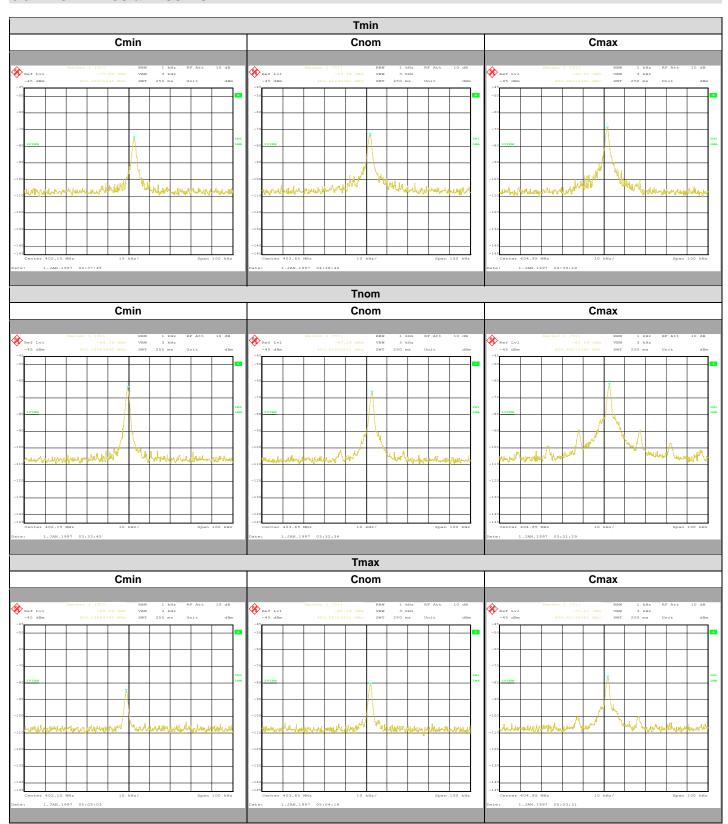
Note: In our system quality, calibration due is more & less 2 month.

|--|

| ⊠None □Divergence: |  |
|--------------------|--|



# 3.6. GRAPHICS & RESULTS





| Temperature           | Tmin     |          |          |          | Tnom     |          | Tmax     |          |          |
|-----------------------|----------|----------|----------|----------|----------|----------|----------|----------|----------|
| Voltage               |          | Vnom     |          |          |          |          |          |          |          |
| Channel               | Cmin     | Cnom     | Cmax     | Cmin     | Cnom     | Cmax     | Cmin     | Cnom     | Cmax     |
| Frequency (MHz)       | 402,1527 | 403,6519 | 404,8517 | 402,1496 | 403,6327 | 404,8527 | 402,1489 | 403,6521 | 404,8519 |
| Frequency error (ppm) | 7,7      | 47,6     | -2,5     | REF      | REF      | REF      | -1,7     | 48,1     | -2,0     |

# 3.7. CONCLUSION

The product SORIN Group Son RCRT - D 1841, SN: 126DD007, in configuration and description presented in this test report, complies with the frequency error measurement of FCC  $\S$  95.627(e) & RSS-243  $\S$  5.3.



# 4. EMISSION BANDWIDTH

# 4.1. TEST CONDITIONS

Test performed by : Mathieu CERISIER

Date of test : 2015/01/15 Ambient temperature : 22°C Relative humidity : 42%

# 4.2. TEST SETUP

| - ' | The | Eaui | pment | under | Test i | is | installed: |
|-----|-----|------|-------|-------|--------|----|------------|
|-----|-----|------|-------|-------|--------|----|------------|

In the climatic chamber

On a table

☐ In an anechoic chamber

-Measurement is performed with a spectrum analyzer

☐ On the EUT conducted access

The spectrum analyzer is used to find the emission bandwidth. Detector peak



Photograph for Emission Bandwidth





Photograph for Emission Bandwidth

#### 4.3. LIMIT

Emission bandwidth shall not exceed 300 kHz. If two or more devices that operate in a given MICS communications session operate in different portions of the 402 MHz to 405 MHz band, their combined emission bandwidths shall not exceed 300 kHz. This limits spectrum usage to a maximum of 300 kHz in any single MICS communications session. The 300 kHz limitation may be exceeded briefly due to intermittent transmissions that may occur when operating channel acquisitions or changes are required to maintain a communications session.

All emissions from each device that fall outside its emission bandwidth but do fall within the 402 MHz to 405 MHz band shall be attenuated at least 20dB.

In addition, emissions from a device operating in the low duty cycle low power mode in the band 403,5MHz to 403,8MHz must be attenuated at least 20 dB at the band edges, 403,5MHz and 403,8MHz.



# 4.4. TEST EQUIPMENT LIST

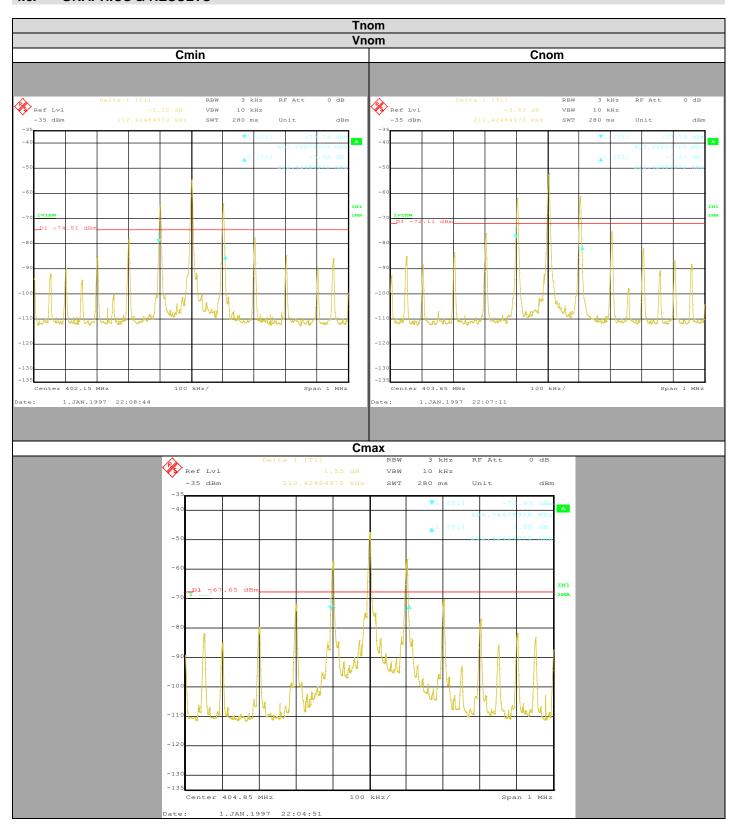
| DESCRIPTION        | MANUFACTURER    | MODEL  | N° LCIE  | Cal_Date      | Cal_Due       |
|--------------------|-----------------|--------|----------|---------------|---------------|
|                    |                 |        |          | Verified with | Verified with |
| Climatic Chamber   | SECASI          | SLT34  | D1024029 | Temperature   | Temperature   |
|                    |                 |        |          | Sensor        | Sensor        |
| EMI receiver       | ROHDE & SCHWARZ | ESI40  | A2642010 | 2014/02       | 2015/02       |
| Temperature Sensor | AOIP            | TM6630 | B4041042 | 2014/12       | 2015/12       |

Note: In our system quality, calibration due is more & less 2 month.

| <i>4.5.</i> | DIVERGENCE, | ADDITION OR SUPPRESSION ON THE TEST SPECIFICATION |
|-------------|-------------|---|
| ⊠Non        | e           | Divergence:                                       |



# 4.6. GRAPHICS & RESULTS





| Temperature              | Tnom    |         |         |  |  |
|--------------------------|---------|---------|---------|--|--|
| Voltage                  | Vnom    |         |         |  |  |
| Channel                  | Cmin    | Cnom    | Cmax    |  |  |
| Emission bandwidth (kHz) | 212.424 | 212.424 | 212.424 |  |  |

# 4.7. CONCLUSION

The product SORIN Group Son RCRT - D 1841, SN: 126DD007, in configuration and description presented in this test report, complies with the emission bandwidth measurement of FCC  $\S$  95.633(e) & RSS-243  $\S$  5.1.



#### 5. **OCCUPIED BANDWIDTH**

#### 5.1. **TEST CONDITIONS**

Test performed by : Mathieu CERISIER

Date of test : 2015/01/15 Ambient temperature : 25°C Relative humidity : 29%

#### **TEST SETUP** 5.2.

- The Equipment under Test is installed:  $\begin{tabular}{l} \begin{tabular}{l} \begin{t$ 

On a table

☐ In an anechoic chamber

-Measurement is performed with a spectrum analyzer

On the EUT conducted access

With a test fixture

The product has been tested according to the RSS-GEN § 6.6 reference method. Detector peak



Photograph for Occupied Bandwidth





Photograph for Occupied Bandwidth

# 5.3. LIMIT

No Limit

# 5.4. TEST EQUIPMENT LIST

| DESCRIPTION        | MANUFACTURER    | MODEL  | N° LCIE  | Cal_Date                               | Cal_Due                                |
|--------------------|-----------------|--------|----------|--|--|
| Climatic Chamber   | SECASI          | SLT34  | D1024029 | Verified with<br>Temperature<br>Sensor | Verified with<br>Temperature<br>Sensor |
| EMI receiver       | ROHDE & SCHWARZ | ESI40  | A2642010 | 2014/02                                | 2015/02                                |
| Temperature Sensor | AOIP            | TM6630 | B4041042 | 2014/12                                | 2015/12                                |

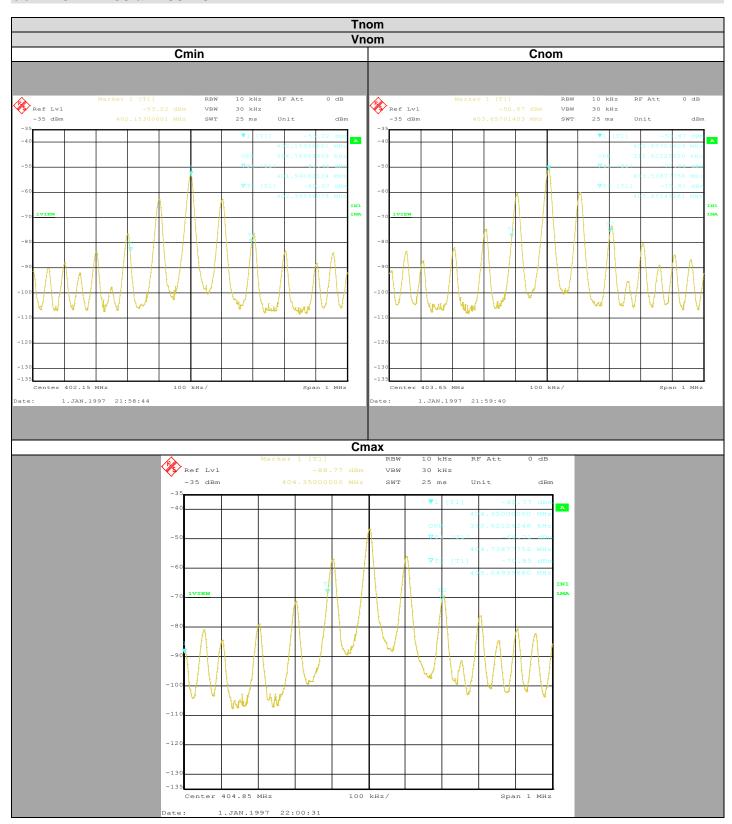
Note: In our system quality, calibration due is more & less 2 month.

| 5.5. DIVER | GENCE. A | ADDITION C | DR SUI | PRESSI | ON ON | THE 1 | TEST SI | PECIFIC | CATIO | N |
|------------|----------|------------|--------|--------|-------|-------|---------|---------|-------|---|
|------------|----------|------------|--------|--------|-------|-------|---------|---------|-------|---|

| None | Divergence: |  |  |
|------|-------------|--|--|
|      |             |  |  |



# 5.6. GRAPHICS & RESULTS





| Temperature              | Tnom    |         |         |  |  |
|--------------------------|---------|---------|---------|--|--|
| Voltage                  | Vnom    |         |         |  |  |
| Channel                  | Cmin    | Cnom    | Cmax    |  |  |
| Occupied Bandwidth (kHz) | 384.769 | 312.625 | 310.621 |  |  |

# 5.7. CONCLUSION

The product SORIN Group Son RCRT - D 1841, SN: 126DD007, in configuration and description presented in this test report, complies with the occupied bandwidth measurement of RSS-Gen § 6.6.



| 6.1. TEST CONDIT  | TIONS  |
|---|--|
| Test performed by<br>Date of test<br>Ambient temperature<br>Relative humidity | : Laurent DENEUX<br>: November 27th, 2014<br>: 18°C<br>: 47%   |
| 6.2. TEST SETUP   |  |
| - The Equipment Unde<br>☐ FAR<br>☐ SAR<br>☑ OATS                              | r Test is installed:   |
| - Distance between EU ☐ 3m ☑ 10m  | JT and the measuring antenna is:   |
| the EUT is found by th  With measurement                                      | pove the ground reference plane on an isolating table and the maximum emitted power value from e rotation of the 360°turntable and: antenna height at 1.5m from the ground reference plane surement antenna height between 1m and 4m from the ground reference plane |
| equipment under test. the substitution anteni                                 | The substitution antenna is powered by signal generator through RF cables. The input signal on the is adjusted in order to obtain the same value found in the maximum emitted power search.  |

Mean power at the output of the transmitter and product antenna gain (A+G) are deduced after correction due to the gain of the substitution antenna and the RF cables loss between the signal generator and the substitution antenna

The Equivalent Isotropic Radiated Power (EIRP in dBm) is defined with the following formula:

EIRP = A+G

A (dBm): peak power at the output of the transmitter

G (dBi): product antenna gain

A+G: Measured in radiated by substitution method

Detector peak





Photograph for Transmitter output power

#### 6.3. LIMIT

The EIRP of ULP-AMI and/or ULP-AMI-P equipment that operates as part of system that incorporates a monitoring system to select the frequency of operation using LBT and AFA shall not exceed  $25 \,\mu W$ .

The EIRP of ULP-AMI transmitters operating on any frequency in the band 403,5 MHz to 403,8 MHz shall not exceed 100nW unless the frequency of operation in this band has been selected by a monitoring system using LBT and AFA. The duty cycle for any transmitter operating in the LDC mode is limited to 0,01%.



# 6.4. TEST EQUIPMENT LIST

| Apparatus           | Trade Mark      | Туре              | Registration number | Cal_Date | Cal_Due |
|---------------------|-----------------|-------------------|---------------------|----------|---------|
| EMI receiver        | ROHDE & SCHWARZ | ESI40 1088 740K40 | A2642010            | 2014/02  | 2015/02 |
| Bilog antenna       | CHASE           | CBL 6112A         | C2040040            | 2014/04  | 2015/04 |
| Logperiodic antenna | ROHDE & SCHWARZ | HL 023 A2         | C2040001            | 2014/05  | 2015/05 |
| Signal Generator    | ROHDE & SCHWARZ | SMY02             | A5442014            | 2014/04  | 2015/04 |
| Cable               | -               | -                 | A5329449            | 2014/09  | 2015/09 |
| Cable               | -               | -                 | A5329368            | 2014/04  | 2015/04 |
| cable               | -               | -                 | A5329444            | 2014/09  | 2015/09 |
| Cable               | -               | -                 | A5329362            | 2014/03  | 2015/04 |
| Cable               | -               | -                 | A5329442            | 2014/09  | 2015/09 |
| OATS                | L.C.I.E.        | -                 | F2000400            | 2014/06  | 2015/06 |

| 6.5. | DIVERGENCE | ADDITION OR SUPPRESSION ON THE TEST SPECIFICATION |
|------|------------|---|
|      |            |   |
| ⊠Nor | ne         | Divergence:                                       |
|      |            |   |
| 6.6. | RESULTS    |   |

| Tnom      |                       |           |                    |            |           |  |  |
|-----------|-----------------------|-----------|--------------------|------------|-----------|--|--|
| Vnom      |                       |           |                    |            |           |  |  |
| Frequency | Generator level (dBm) | Loss (dB) | Antenna gain (dBi) | EIRP (dBm) | EIRP (μW) |  |  |
| 402.15MHz | -46.0                 | 2.4       | 5.1                | -43,26     | 0,047     |  |  |
| 403.66MHz | -47.0                 | 2.4       | 5.2                | -44,26     | 0,037     |  |  |
| 404.85MHz | -45.0                 | 2.4       | 5.2                | -42,26     | 0,059     |  |  |

# 6.7. CONCLUSION

The product SORIN Group Son RCRT - D 1841, SN: 126DD007, in configuration and description presented in this test report, complies with the transmitter output power measurement of FCC § 95.639(f) & RSS-243 § 5.4.



# 7. TRANSMITTER UNWANTED EMISSIONS

#### 7.1. TEST CONDITIONS

Test performed by : Laurent DENEUX & Mathieu CERISIER Date of test : 2014/10/06 & 2014/08/19 to 2014/12/16

Ambient temperature : 18°C & 23°C Relative humidity : 51% & 43%

#### 7.2. TEST SETUP

☐SAR ⊠OATS

- Distance between EUT and the measuring antenna is:

□3m ⊠10m

- Choice of measuring antenna below 1GHz:

- Choice of measuring antenna above 1GHz:

⊠Horn

The product has been tested according to ANSI C63.10 (2009). Test is performed in horizontal (H) and vertical (V) polarization. Measurement bandwidth was 120kHz below 1GHz and 1MHz above 1GHz. The level has been maximised by the turntable rotation of 360 degrees range on the 3 axis of EUT. Antenna height search was performed from 1 to 4m.



Photograph for Transmitter unwanted emissions



# *7.3.* LIMIT

Transmitter unwanted emissions from MICS devices more than 250kHz outside of the 402-405 MHz band shall not exceed the field strength limits specified below:

| Frequencies       | Limit at 10m (µV/m) | Limit at 3m (µV/m) | Limit at 3m (µV/m) |
|-------------------|---------------------|--------------------|--------------------|
| 30MHz to 88MHz    | 29.55dBµV/m QPeak   | 40dBμV/m QPeak     | 100μV/m QPeak      |
| 88MHz to 216MHz   | 33.05dBµV/m QPeak   | 43.5dBµV/m QPeak   | 150µV/m QPeak      |
| 216MHz to 960MHz  | 35.55dBµV/m QPeak   | 46dBµV/m QPeak     | 200µV/m QPeak      |
| 960MHz to 1000MHz | 43.45dBµV/m QPeak   | 53.9dBµV/m QPeak   | 500μV/m QPeak      |
| Above 1000MHz     | 63.45dBµV/m Peak    | 73.9dBµV/m Peak    | 5000μV/m Peak      |
|                   | 43.45dBµV/m Average | 53.9dBµV/m Average | 500μV/m Average    |

Transmitter unwanted emissions within the 402-405MHz MICS band which are more than 150kHz away from the centre frequency of the spectrum, and the transmissions that occupy up to 250kHz above and below the band shall be attenuated at least 20dB below the maximum transmitter output power.



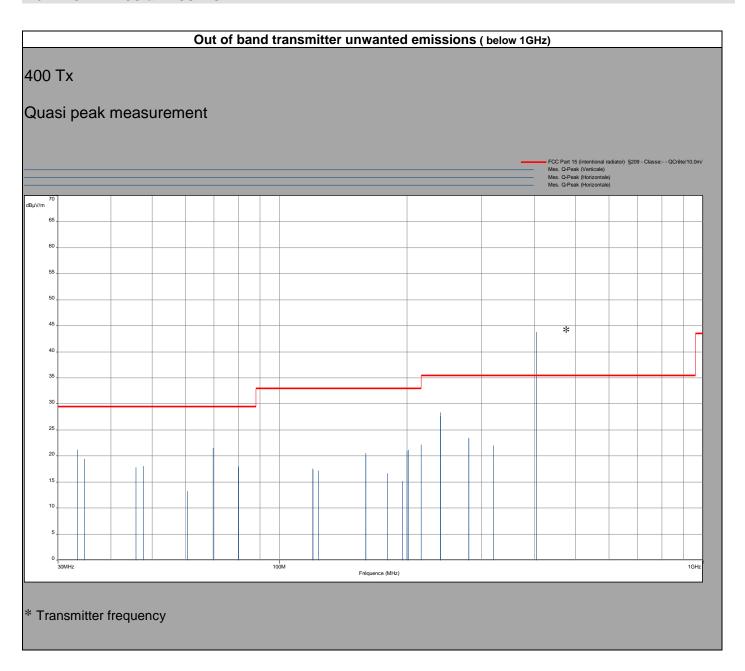
# 7.4. TEST EQUIPMENT LIST

| DESCRIPTION        | MANUFACTURER    | MODEL                | N° LCIE  | Cal_Date | Cal_Due |
|--------------------|-----------------|----------------------|----------|----------|---------|
| EMI receiver       | ROHDE & SCHWARZ | ESI40 1088<br>740K40 | A2642010 | 2014/02  | 2015/02 |
| Bilog antenna      | CHASE           | CBL 6112A            | C2040040 | 2014-04  | 2015-04 |
| Cable              | -               | -                    | A5329449 | 2014-09  | 2015-09 |
| Cable              | -               | -                    | A5329368 | 2014-03  | 2015-03 |
| Cable              | -               | -                    | A5329444 | 2014-09  | 2015-09 |
| Cable              | -               | -                    | A5329542 | 2014-01  | 2015-01 |
| OATS               | L.C.I.E.        | ı                    | F2000400 | 2014-06  | 2015-06 |
| Horn Antenna       | EMCO            | 3115                 | C2042016 | 2014-04  | 2015-04 |
| Preampli           | HEWLETT PACKARD | 8449B                | A4069002 | 2014-04  | 2015-04 |
| Climatic Chamber   | MPC             | F65/350L             | D1025035 | 2013/12  | 2014/12 |
| EMI receiver       | ROHDE & SCHWARZ | FSIQ7                | A4060040 | 2013/11  | 2014/11 |
| Temperature Sensor | HP              | 34970A               | A6440070 | 2014/01  | 2016/01 |

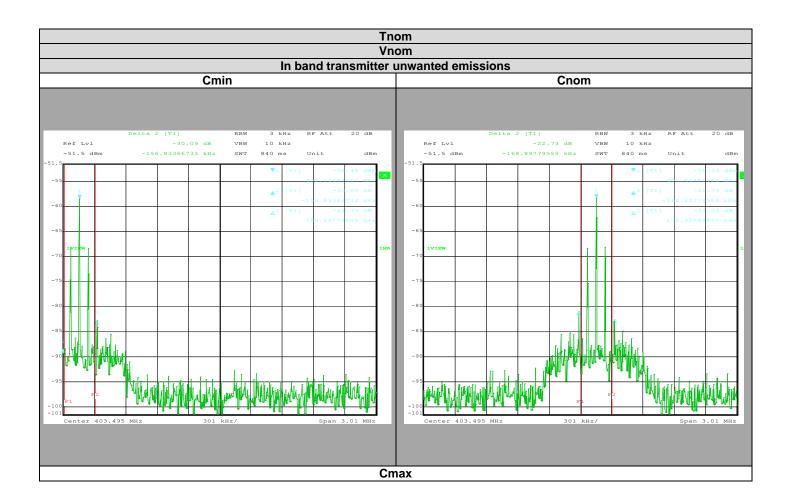
| 7.5. | DIVERGENCE, ADDITION OR SUPPRESSION ON THE TEST SPECIFICATION |
|------|---|
|      |   |
| Non  | e Divergence:   |



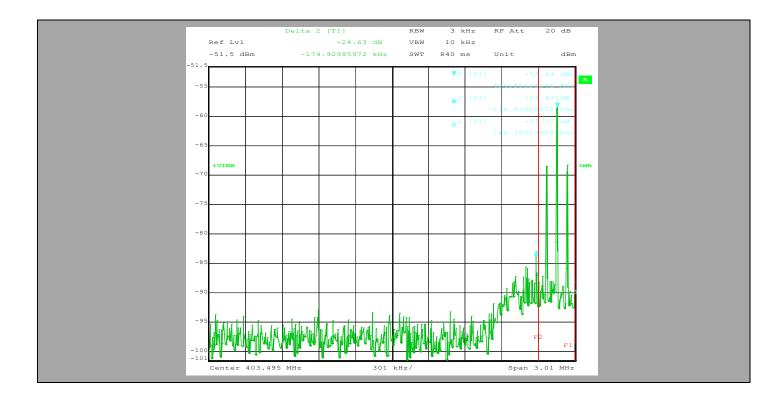
# 7.6. GRAPHICS & RESULTS

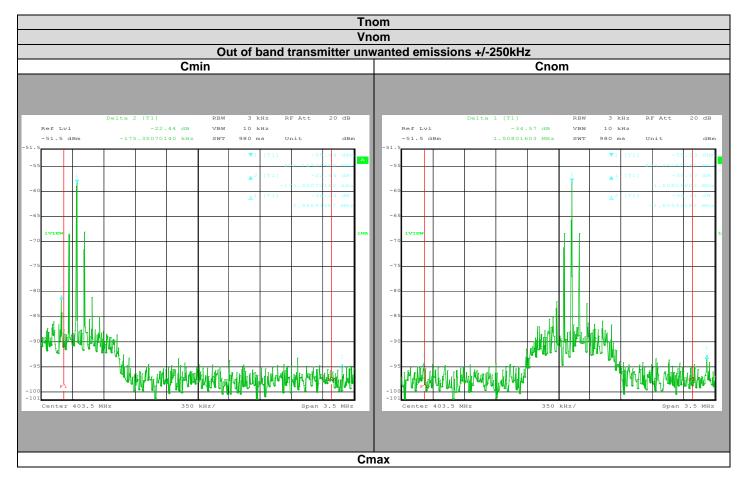




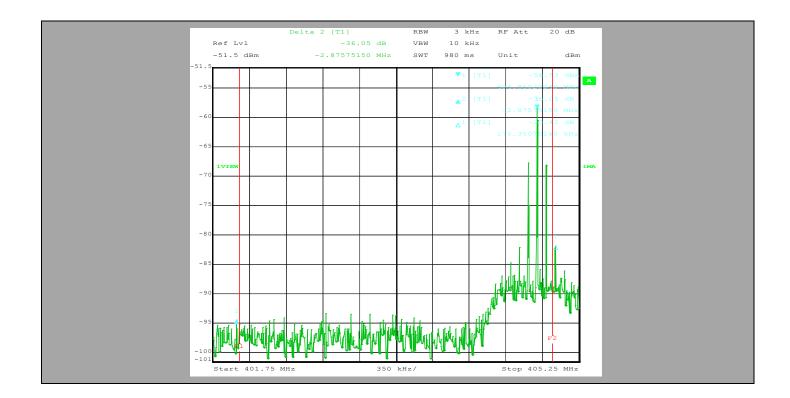














| Out of band transmitter unwanted emissions |                   |                              |                              |  |  |
|--|-------------------|------------------------------|------------------------------|--|--|
|  | В                 | elow 1GHz                    |                              |  |  |
| Polarization                               | Frequencies (MHz) | Quasi-Peak Level<br>(dBµV/m) | Quasi-Peak Limit<br>(dBµV/m) |  |  |
| Vertical                                   | 33.3              | 21.26                        | 29.5                         |  |  |
| Vertical                                   | 34.6              | 19.45                        | 29.5                         |  |  |
| Vertical                                   | 45.8              | 17.85                        | 29.5                         |  |  |
| Vertical                                   | 47.8              | 18.1                         | 29.5                         |  |  |
| Vertical                                   | 60.6              | 13.25                        | 29.5                         |  |  |
| Vertical                                   | 69.7              | 21.54                        | 29.5                         |  |  |
| Vertical                                   | 80                | 17.67                        | 29.5                         |  |  |
| Vertical                                   | 120               | 17.58                        | 33                           |  |  |
| Vertical                                   | 160               | 20.59                        | 33                           |  |  |
| Vertical                                   | 180               | 16.66                        | 33                           |  |  |
| Vertical                                   | 195.4             | 15.24                        | 33                           |  |  |
| Vertical                                   | 201.3             | 21.18                        | 33                           |  |  |
| Vertical                                   | 216               | 22.2                         | 33                           |  |  |
| Vertical                                   | 240               | 28.38                        | 35.5                         |  |  |
| Vertical                                   | 280               | 23.54                        | 35.5                         |  |  |
| Horizontal                                 | 80                | 18.05                        | 29.5                         |  |  |
| Horizontal                                 | 120               | 17.37                        | 33                           |  |  |
| Horizontal                                 | 123.7             | 17.25                        | 33                           |  |  |
| Horizontal                                 | 160               | 20.14                        | 33                           |  |  |
| Horizontal                                 | 200               | 21                           | 33                           |  |  |
| Horizontal                                 | 240               | 27.7                         | 35.5                         |  |  |
| Horizontal                                 | 280               | 23.29                        | 35.5                         |  |  |
| Horizontal                                 | 320               | 22.03                        | 35.5                         |  |  |



# Detector peak

| Out of band +/-250kHz transmitter unwanted emissions     |       |       |             |  |  |  |  |
|--|-------|-------|-------------|--|--|--|--|
| Channel Level (dB) at Fmin Level (dB) at Fmax Limit (dB) |       |       |             |  |  |  |  |
| Cmin   | 22,44 | 36,23 | At least 20 |  |  |  |  |
| Cnom   | 36,11 | 34,57 | At least 20 |  |  |  |  |
| Cmax   | 36,05 | 23,42 | At least 20 |  |  |  |  |

# Detector peak

| In band transmitter unwanted emissions                   |  |       |             |  |  |  |  |
|--|--|-------|-------------|--|--|--|--|
| Channel Level (dB) at Fmin Level (dB) at Fmax Limit (dB) |  |       |             |  |  |  |  |
| Cmin 30,09   |  | 24,33 | At least 20 |  |  |  |  |
| Cnom         22,73           Cmax         24,63          |  | 24,33 | At least 20 |  |  |  |  |
|  |  | 31,07 | At least 20 |  |  |  |  |

# 7.7. CONCLUSION

The product SORIN Group Son RCRT - D 1841, SN: 126DD007, in configuration and description presented in this test report, complies with the Unwanted Emission into Restricted Bands measurement of FCC § 95.635(d) & RSS-243 § 5.5.



| 8. | DECEMED  | CDUDIOUS | EMICCIONIC |
|----|----------|----------|------------|
| 0. | RECEIVER | SPURIOUS | FINISSIONS |

# 8.1. TEST CONDITIONS

Test performed by : Laurent DENEUX
Date of test : 2014/11/27
Ambient temperature : 18°C
Relative humidity : 51%

# 8.2. TEST SETUP

| - | The | Equipment | under | Test is | installed: |
|---|-----|-----------|-------|---------|------------|
|   |     |           |       |         |            |

□SAR ⊠OATS

- Distance between EUT and the measuring antenna is:

- Choice of measuring antenna below 1GHz:

- Choice of measuring antenna above 1GHz:

⊠Horn

The product has been tested according to ANSI C63.10 (2009). Test is performed in horizontal (H) and vertical (V) polarization. Measurement bandwidth was 120kHz below 1GHz and 1MHz above 1GHz. The level has been maximised by the turntable rotation of 360 degrees range on the 3 axis of EUT. Antenna height search was performed from 1 to 4m.



Photograph for Receiver spurious emissions



| 0 | .3 |  | L | ı | п | V | П | П | п |
|---|----|--|---|---|---|---|---|---|---|
|   |    |  |   |   |   |   |   |   |   |
| v |    |  | _ | ш | ш | ш | ш | ш | ш |

Receiver spurious emissions shall not exceed value below:

 $\begin{array}{lll} 30 \text{MHz to } 88 \text{MHz:} & 29.5 \text{dB}\mu\text{V/m QPeak} \\ 88 \text{MHz to } 216 \text{MHz:} & 33 \text{dB}\mu\text{V/m QPeak} \\ 216 \text{MHz to } 960 \text{MHz:} & 35.5 \text{dB}\mu\text{V/m QPeak} \\ 960 \text{MHz to } 1000 \text{MHz:} & 43.5 \text{dB}\mu\text{V/m QPeak} \\ \text{Above } 1000 \text{MHz:} & 63.5 \text{dB}\mu\text{V/m Peak} \\ \end{array}$ 

43.5dBµV/m Average

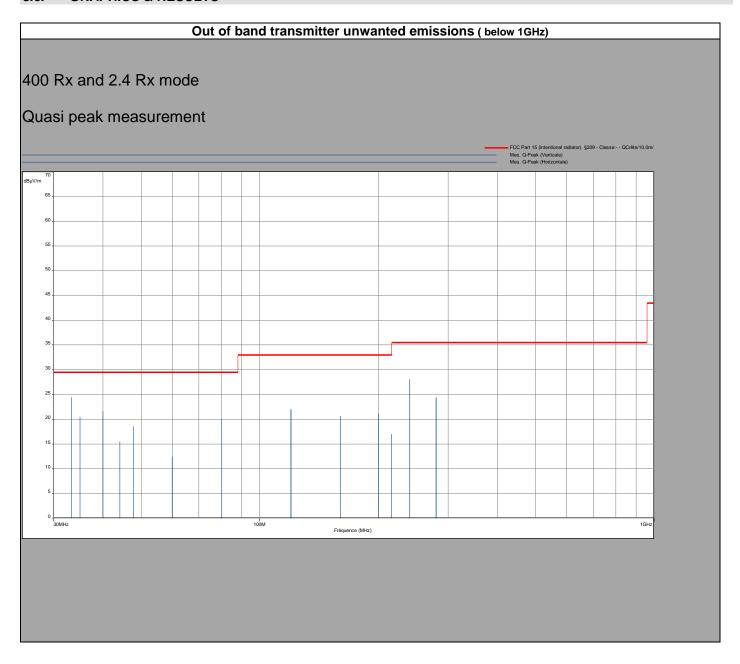
# 8.4. TEST EQUIPMENT LIST

| Apparatus     | Trade Mark         | Туре                 | Registration number | Cal_Date | Cal_Due |
|---------------|--------------------|----------------------|---------------------|----------|---------|
| EMI receiver  | ROHDE &<br>SCHWARZ | ESI40 1088<br>740K40 | A2642010            | 2014/02  | 2015/02 |
| Bilog antenna | CHASE              | CBL 6112A            | C2040040            | 2014-04  | 2015-04 |
| Cable         | =                  | -                    | A5329449            | 2014-09  | 2015-09 |
| Cable         | -                  | -                    | A5329368            | 2014-03  | 2015-03 |
| Cable         | -                  | -                    | A5329444            | 2014-09  | 2015-09 |
| Cable         | -                  | -                    | A5329542            | 2014-01  | 2015-01 |
| OATS          | L.C.I.E.           | -                    | F2000400            | 2014-06  | 2015-06 |
| Horn Antenna  | EMCO               | 3115                 | C2042016            | 2014-04  | 2015-04 |
| Preampli      | HEWLETT<br>PACKARD | 8449B                | A4069002            | 2014-04  | 2015-04 |

| <i>8.5.</i> | DIVERGENCE, ADDITION OR SUPPRESSION ON THE TEST SPECIFICATION |
|-------------|---|
| Non         | e Divergence:   |



# 8.6. GRAPHICS & RESULTS





| Out of band transmitter unwanted emissions |                   |                              |                              |  |  |  |
|--|-------------------|------------------------------|------------------------------|--|--|--|
|  | Below 1GHz        |                              |                              |  |  |  |
| Polarization                               | Frequencies (MHz) | Quasi-Peak Level<br>(dBµV/m) | Quasi-Peak Limit<br>(dBµV/m) |  |  |  |
| Vertical                                   | 33.3              | 24.46                        | 29.5                         |  |  |  |
| Vertical                                   | 35                | 20.54                        | 29.5                         |  |  |  |
| Vertical                                   | 40                | 21.7                         | 29.5                         |  |  |  |
| Vertical                                   | 44.2              | 15.49                        | 29.5                         |  |  |  |
| Vertical                                   | 47.8              | 18.59                        | 29.5                         |  |  |  |
| Vertical                                   | 59.9              | 12.48                        | 29.5                         |  |  |  |
| Vertical                                   | 80                | 17.92                        | 29.5                         |  |  |  |
| Vertical                                   | 120               | 21.93                        | 33                           |  |  |  |
| Vertical                                   | 160               | 20.6                         | 33                           |  |  |  |
| Vertical                                   | 216               | 17.05                        | 33                           |  |  |  |
| Vertical                                   | 240               | 28.14                        | 355                          |  |  |  |
| Vertical                                   | 280               | 24.37                        | 35.5                         |  |  |  |
| Horizontal                                 | 80                | 20.2                         | 29.5                         |  |  |  |
| Horizontal                                 | 120               | 22.04                        | 33                           |  |  |  |
| Horizontal                                 | 160               | 20.68                        | 33                           |  |  |  |
| Horizontal                                 | 200               | 21.13                        | 33                           |  |  |  |
| Horizontal                                 | 240               | 27.7                         | 35.5                         |  |  |  |

# 8.7. CONCLUSION

The product SORIN Group Son RCRT - D 1841, SN: 126DD007, in configuration and description presented in this test report, complies with the receiver spurious emissions measurement of FCC 15.109 & RSS-243 § 5.6.



# 9. SAR EVALUATION

# 9.1. TEST CONDITIONS

Test performed by : Mathieu CERISIER

Date of test : 2015/07/31

Ambient temperature : 26 Relative humidity : 32%

# 9.2. TEST SETUP

| - T | he. | Equi | pment | under | Test i | is i | instal | led | : |
|-----|-----|------|-------|-------|--------|------|--------|-----|---|
|-----|-----|------|-------|-------|--------|------|--------|-----|---|

☐ In the climatic chamber

On a table

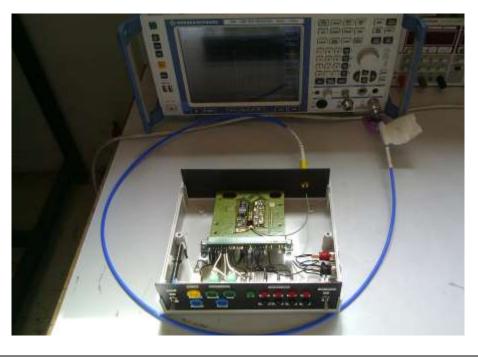
☐ In an anechoic chamber

# -Measurement is performed with a spectrum analyzer

☑ On the EUT conducted access

With a test fixture

The spectrum analyzer marker peak functions is used to find the maximum rf conducted output power Detector peak



Photograph for RF conducted output power



#### 9.3. LIMIT

#### RSS-102 Issue 5 March 2015:

2.5.1 Exemption Limits for Routine Evaluation – SAR Evaluation

For medical implants devices, the exemption limit for routine evaluation is set at 1 mW. The output power of a medical implants device is defined as the higher of the conducted or e.i.r.p to determine whether the device is exempt from the SAR evaluation.

#### FCC:

KDB 447498 section 4.2.4:

4.2.4. Transmitters implanted in the body of a user

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 and fully justified in a SAR analysis report, in lieu of the SAR measurement or numerical simulation, according to design and implementation requirements of the device.

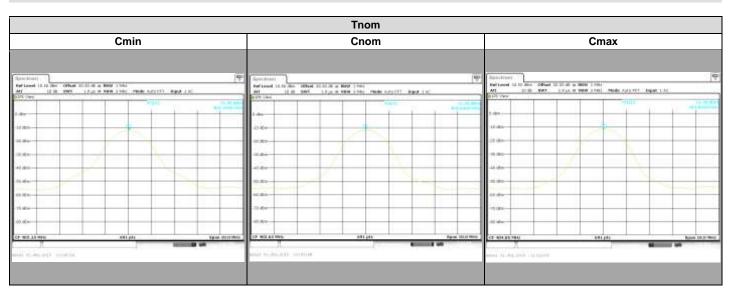
#### 9.4. TEST EQUIPMENT LIST

| DESCRIPTION           | MANUFACTURER             | MODEL                    | N° LCIE  | Cal_Date | Cal_Due |
|-----------------------|--------------------------|--------------------------|----------|----------|---------|
| EMI test receiver     | R&S                      | ESR                      | A2642023 | 03/2015  | 03/2016 |
| RF cable & Attenuator | Télédyne & MINI CIRCUITS | 920-0202-024 &<br>FW-20+ | A5329674 | 10/2014  | 10/2015 |

# 9.5. DIVERGENCE, ADDITION OR SUPPRESSION ON THE TEST SPECIFICATION

| ⊠None | Divergence: |
|-------|-------------|

#### 9.6. GRAPHICS & RESULTS





| Temperature                     | Tnom     |          |          |  |
|---------------------------------|----------|----------|----------|--|
| Voltage                         | Vnom     |          |          |  |
| Channel                         | Cmin     | Cnom     | Cmax     |  |
| RF conducted output power (dBm) | -11,98   | -11,59   | -11,4    |  |
| RF conducted output power (mW)  | 0,063    | 0,069    | 0,072    |  |
| EIRP (dBm)                      | -43,26   | -44,26   | -42,26   |  |
| EIRP (mW)                       | 0,000047 | 0,000037 | 0,000059 |  |

# 9.7. CONCLUSION

The product SORIN Group Son RCRT - D 1841, in configuration and description presented in this test report, is excluded of SAR evaluation.



# 10. UNCERTAINTIES CHART

| Kind of test                      | Measurement uncertainties (k=2) ±x(dB) / (Hz) | Limit for<br>uncertainties<br>±y(dB) |
|-----------------------------------|---|--------------------------------------|
| REQUIREMENTS                      |   |                                      |
| RF output power, conducted        | ±0.6 dB                                       | ±1,5 dB                              |
| Power Spectral Density, conducted | ±0.6 dB                                       | ±1,5 dB                              |
| Unwanted Emissions, conducted     | ±0.6 dB                                       | ±1,5 dB                              |
| Radiated emissions                |   | ·                                    |
| Frequency < 1000 MHz              | ±3.9 dB                                       | ±6 dB                                |
| Frequency > 1000 MHz              | ±3.1 dB                                       |                                      |
| Temperature                       | ±0.5°C  | ±1°C                                 |
| Humidity                          | ±2.5 %  | ±5 %                                 |