

Report on the FCC and IC Testing of the INTEGRA Biosciences AG

Model: IDT305MT

In accordance with FCC 47 CFR Part 15 C
and ISED RSS-GEN and ISED RSS-102

Prepared for: INTEGRA Biosciences AG
Tardisstr. 201
7205 Zizers
Switzerland

FCC ID: 2BAQ7-191730RFIDT
IC: 29295-191730RFIDT



Product Service

Add value.
Inspire trust.

COMMERCIAL-IN-CONFIDENCE

Date: 2023-05-25

Document Number: TR-713297030-01 | Revision 3

RESPONSIBLE FOR	NAME	DATE	SIGNATURE
Project Management	Michael Ingerl	2023-05-25	 SIGN-ID 795125
Authorised Signatory	Alex Fink	2023-05-25	 SIGN-ID 795331

Signatures in this approval box have checked this document in line with the requirements of TÜV SÜD Product Service document control rules.

Engineering Statement:

This measurement shown in this report were made in accordance with the procedures described on test pages.

All reported testing was carried out on a sample equipment to demonstrate limited compliance with with FCC 47 CFR Part 15 C and ISED RSS-102 and RSS-GEN.

The sample tested was found to comply with the requirements in the tested parts

RESPONSIBLE FOR	NAME	DATE	SIGNATURE
Testing	Michael Ingerl	2023-05-25	 SIGN-ID 795126

Laboratory Accreditation

DAkkS Reg. No. D-PL-11321-11-03

DAkkS Reg. No. D-PL-11321-11-04

Laboratory recognition

Registration No. BNetzA-CAB-16/21-15

Industry Canada test site registration

3050A-2

Executive Statement:

A sample of this product was tested and found to be compliant with FCC 47 CFR Part 15 C:2021 and ISED RSS-102:2015 + A1:2021 and ISED RSS-Gen:2018 + A1:2019 + A2:2021 in the tested parts

DISCLAIMER AND COPYRIGHT

This non-binding report has been prepared by TÜV SÜD Product Service with all reasonable skill and care. The document is confidential to the potential Client and TÜV SÜD Product Service. No part of this document may be reproduced without the prior written approval of TÜV SÜD Product Service. © 2023 TÜV SÜD Product Service.

Trade Register Munich
HRB 85742
VAT ID No. DE129484267
Information pursuant to Section 2(1)
DL-InfoV (Germany) at
www.tuvsud.com/imprint

Managing Directors:
Walther Reithmaier (Sprecher / CEO)
Patrick van Welij

Phone: +49 (0) 9421 56 82-0
Fax: +49 (0) 9421 56 82-199
www.tuvsud.com

TÜV SÜD Product Service GmbH
Äußere Frühlingsstraße 45
94315 Straubing
Germany



Content

1	Report Summary.....	2
1.1	Modification Report.....	2
1.2	Introduction	2
1.3	Brief Summary of Results	3
1.4	Product Information	4
1.5	Test Configuration	5
1.6	EUT Modifications Record	5
1.7	Test Location	6
2	Test Details.....	7
2.1	RF Exposure Exemption.....	7
3	Measurement Uncertainty	11

Annexes:

TR-713297030-01 rev1 Annex A: Test Setup Photos



1 Report Summary

1.1 Modification Report

Alternations and additions of this report will be issued to the holders of each copy in the form of a complete document.

<i>Revision</i>	<i>Description of changes</i>	<i>Date of Issue</i>
0	First Issue	2023-04-18
1	Evaluation according to KDB 447498 D01 and RSS 102 2.5.1	2023-04-28
2	Added calculation of limits	2023-05-10
3	Changed at chapter 2.1.6 the limit	2023-05-25

Table 1: Report of Modifications

1.2 Introduction

Applicant	INTEGRA Biosciences AG
Manufacturer	iDTRONIC GmbH
Model Number(s)	IDT305MT
Serial Number(s)	---
Hardware Version(s)	---
Software Version(s)	---
Number of Samples Tested	1
Test Specification(s) / Issue / Date	FCC 47 CFR, Part 1, § 1.1307: 2021, KDB 447498 D01, 4.3 and ISED RSS-102, Issue 5, Amd. 1: 2021
Test Plan/Issue/Date	---
Order Number	5784970-1
Date of Receipt of EUT	2022-09-14
Start of Test	2022-09-21
Finish of Test	2022-09-21
Name of Engineer(s)	Patrick Müller, Alexander Deese
Related Document(s)	ANSI C63.10:2013



1.3 Brief Summary of Results

A brief summary of the tests carried out in accordance with FCC 47 CFR, Part 1, § 1.1307, KDB 447498 D01, 4.3 and ISED RSS-102 is shown below.

<i>Section</i>	<i>Specification Clause</i>	<i>Test Description</i>	<i>Result</i>
2.1	(i)(B)	RF Exposure Exemption	Pass

Table 2: Results according to FCC 47 CFR, Part 1, § 1.1307(b)(3)

<i>Section</i>	<i>Specification Clause</i>	<i>Test Description</i>	<i>Result</i>
2.1	2.5.1	RF Exposure Exemption	Pass

Table 3: Results according to ISED RSS-102



1.4 Product Information

1.4.1 Technical Description

Equipment characteristics		
Type designation:	IDT305MT	
Type of equipment:	RFID Module	
Application ¹ :	Inductive Applications	
Equipment class:	Equipment for fixed use	
Kind of equipment	Transceiver	
Operating Frequency:	13.56 MHz	
Channel spacing:	Wideband	
Number of RF channels:	1	
Antenna:	Integrated Antenna	
Type(s) of Modulation (e.g. BPSK, FSK, ASK, ...)	---	
Power supply:	DC supplied (USB)	
	Nominal:	5 V
	Minimum:	---
	Maximum:	---
	Nominal frequency:	DC



1.5 Test Configuration

The EUT was 5V DC power supplied. RFID worked.

1.6 EUT Modifications Record

The table below details modifications made to the EUT during the test program.
The modifications incorporated during each test are recorded on the appropriate test pages.

Modification State	Description of Modification still fitted to EUT	Modification Fitted By	Date Modification Fitted
0	As supplied by the customer	Not Applicable	Not Applicable

Table 4



Product Service

1.7 Test Location

TÜV SÜD Product Service conducted the following tests at our Straubing test laboratory:

Test Name	Name of Engineer(s)
RF Exposure	Patrick Müller, Alexander Deese

Office Address:

Äußere Frühlingstraße 45
94315 Straubing
Germany



Product Service

2 Test Details

2.1 RF Exposure Exemption

2.1.1 Specification Reference

47 CFR, Part 1, § 1.1307(b)(3)
KDB 447498 D01, 4.3
RSS-102, Issue 5 (2015-03-19) + Amendment 1 (2021-02-02)

2.1.2 Equipment under Test and Modification State

IDT305MT - Modification state 0

2.1.3 Date of Test

2022-09-21



2.1.4 Specification Limits

47 CFR, Part 1, § 1.1307(b)(3)

- (i) For single RF sources (i.e. any single fixed RF source, mobile device, or portable device, as defined in paragraph(b)(2) of this section): A single RF source is exempt if:
- (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);
- (B) Or the available maximum time-averaged power or effective radiate power (ERP), whichever is greater, is less than or equal to the threshold P_{th} (mW) described in the following formula. This method shall only be used at separation distances (cm) from 0.5 cm to 40 cm and at frequencies from 0.3 GHz to 6 GHz (inclusive). P_{th} is given by

$$P_{th}(\text{mW}) = \begin{cases} ERP_{20\text{cm}} (d/20 \text{ cm})^x, & d \leq 20 \text{ cm}; \\ ERP_{20\text{cm}}, & 20 \text{ cm} < d \leq 40 \text{ cm} \end{cases}$$

where

$$x = -\log_{10} \left(\frac{60}{ERP_{20\text{cm}} \sqrt{f}} \right); f \text{ in GHz}$$

and

$$ERP_{20\text{cm}}(\text{mW}) = \begin{cases} 2040 f, & 0.3 \text{ GHz} \leq f < 1.5 \text{ GHz} \\ 3060, & 1.5 \text{ GHz} \leq f \leq 1.5 \text{ GHz} \end{cases}$$

d = the test separation distance (cm);

- (C) Or using the table below and the minimum separation distance (R in meters) from the body of a nearby person for the frequency (f in MHz) at which the source operates, the ERP (watts) is no more than the calculated value described for that frequency. For the exemption in the table to apply, R must be at least $\lambda/2\pi$ where λ is the free-space operating wavelength in meters. If the ERP of a single RF source is not easily obtained, then the available maximum time-averaged power may be used in lieu of ERP if the physical dimensions of the radiating structure(s) do not exceed the electrical length of $\lambda/4$ or if the antenna gain is less than that of a half-wave dipole (1.64 linear value).

RF source frequency (MHz)	Threshold ERP (Watts)
0.3 – 1.34	$1920 R^2$
1.34 – 30	$3450 R^2 / f^2$
30 – 300	$3.83 R^2$
300 – 1500	$0.0128 R^2 f^2$
1500 – 100000	$19.2 R^2$

- (ii) For multiple RF sources: Multiple RF sources are exempt if:
- (A) The available maximum time-averaged power of each source is no more than 1 mW and there is a separation distance of 2 cm 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 in paragraph (b)(3)(i)(A) of this section. Medical implant devices may only use this exemption and that in paragraph (b)(3)(i)(A).
- (B) In case of fixed RF sources operating in the same time-averaging period, or of multiple or portable RF sources within a device in the same time averaging period, if the sum of the fractional contributions to the applicable thresholds is less than or equal to 1 as indicated in the following equation:

$$\sum_{i=1}^a \frac{P_i}{P_{th,i}} + \sum_{j=1}^b \frac{ERP_j}{ERP_{th,j}} + \sum_{k=1}^c \frac{Evaluated_k}{ExposureLimit_k} \leq 1$$



RSS-102, section 2.5.1

SAR evaluation is required if the separation distance between the user and/or bystander and the antenna and/or radiating element of the device is less than or equal to 20 cm, except when the device operates at or below the applicable output power level (adjusted for tune-up tolerance) for the specified separation distance defined in the table below:

<i>f (MHz)</i>	<i>Exemption Limits (mW) at separation distance of</i>									
	<i>≤ 5 mm</i>	<i>10 mm</i>	<i>15 mm</i>	<i>20 mm</i>	<i>25 mm</i>	<i>30 mm</i>	<i>35 mm</i>	<i>40 mm</i>	<i>45 mm</i>	<i>≥ 50 mm</i>
≤ 300	71	101	132	162	193	223	254	284	315	345
450	52	70	88	106	123	141	159	177	195	213
835	17	30	42	55	67	80	92	105	117	130
1900	7	10	18	34	60	99	153	225	316	431
2450	4	7	15	30	52	83	123	173	235	309
3500	2	6	16	32	55	86	124	170	225	290
5800	1	6	15	27	41	56	71	85	97	106

Output power level shall be the higher of the maximum conducted or equivalent isotropically radiated power (e.i.r.p.) source-based, time-averaged output power. For controlled use devices where the 8 W/kg for 1 gram of tissue applies, the exemption limits for route evaluation are multiplied by a factor of 5. For limb-worn devices where the 10 grams value applies, the exemption limits for routine evaluation are multiplied by a factor of 2.5. If the operating frequency of the device is between two frequencies located, linear interpolation shall be applied for the applicable separation distance. For test separation distance less than 5 mm, the exemption limits for a separation distance of 5 mm can be applied to determine if a routine evaluation is required.

For medical implants devices, the exemption limit for routine evaluation is set at 1 mW. The output power of a medical implant 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.



2.1.5 Test Method

The RF Exposure is based on a SAR exemption calculation for a test separation distance as stated in the documentation of the EUT.

2.1.6 Test Results

RFID Evaluation 13.56 MHz

According to §1.1307(b)(3)(i)(A):

Maximum Radiated Field Strength:	54.43 dB μ V/m (at a distance of 3m)
Calculated Equivalent Radiated Power:	0.08 μ W (e.i.r.p.)
Minimum separation distance:	5mm ($\leq$ 50 mm)
Exemption Limit	1 mW
Test result	Pass

According to Industry Canada RSS-102, Issue 5, chapter 2.5:

Maximum Radiated Field Strength:	54.43 dB μ V/m (at a distance of 3m)
Calculated Equivalent Radiated Power:	0.08 μ W (e.i.r.p.)
Minimum separation distance:	$\leq$ 5mm
SAR Evaluation Exemption Limit:	71 mW
Test result	Pass



3 Measurement Uncertainty

For a 95% confidence level, the measurement uncertainties for defined systems are:

The measurement uncertainty in the laboratory is less than or equal to the maximum measurement uncertainty according to CISPR16-4-2: 2011 + A1 + A2 + Cor1 (U_{CISPR}). This normative regulation means that the measured value is also the value to be assessed in relation to the limit value.

<i>Radio Interference Emission Testing</i>		
<i>Test Name</i>	<i>kp</i>	<i>Expanded Uncertainty</i>
Conducted Voltage Emission		
9 kHz to 150 kHz (50Ω/50μH AMN)	2	± 3.8 dB
150 kHz to 30 MHz (50Ω/50μH AMN)	2	± 3.4 dB
100 kHz to 200 MHz (50Ω/5μH AMN)	2	± 3.6 dB
Discontinuous Conducted Emission		
9 kHz to 150 kHz (50Ω/50μH AMN)	2	± 3.8 dB
150 kHz to 30 MHz (50Ω/50μH AMN)	2	± 3.4 dB
Conducted Current Emission		
9 kHz to 200 MHz	2	± 3.5 dB
Magnetic Field strength		
9 kHz to 30 MHz (with loop antenna)	2	± 3.9 dB
9 kHz to 30 MHz (large-loop antenna 2 m)	2	± 3.5 dB
Radiated Emission		
30 MHz to 300 MHz	2	± 4.9 dB
300 MHz to 1 GHz	2	± 5.0 dB
1 GHz to 6 GHz	2	± 4.6 dB
Test distance 10 m		
30 MHz to 300 MHz	2	± 4.9 dB
300 MHz to 1 GHz	2	± 4.9 dB
The expanded uncertainty reported according to CISPR16-4-2: 2011 + A1 + A2 + Cor1 is based on a standard uncertainty multiplied by a coverage factor of $k_p = 2$, providing a level of confidence of $p = 95.45\%$		

Table 5 Measurement uncertainty based on CISPR 16-4-2



<i>Radio Interference Emission Testing</i>		
<i>Test Name</i>	<i>kp</i>	<i>Expanded Uncertainty</i>
Occupied Bandwidth	2	± 5 %
Conducted Power		
9 kHz ≤ f < 30 MHz	2	± 1.0 dB
30 MHz ≤ f < 1 GHz	2	± 1.5 dB
1 GHz ≤ f ≤ 40 GHz	2	± 2.5 dB
1 MS/s power sensor (TS8997)	2	± 1.5 dB
Occupied Bandwidth	2	± 5 %
Power Spectral Density	2	± 3.0 dB
Radiated Power		
9 kHz ≤ f < 26.5 GHz	2	± 5.6 dB
26.5 GHz ≤ f < 60 GHz	2	± 8.0 dB
60 GHz ≤ f < 325 GHz	2	± 10 dB
Conducted Spurious Emissions	2	± 3.0 dB
Radiated Spurious Emissions	2	± 6.0 dB
Voltage		
DC	2	± 1.0 %
AC	2	± 2.0 %
Time (automatic)	2	± 5 %
Frequency	2	± 10 ⁻⁷
The expanded uncertainty reported according to to ETSI TR 100 028:2001 is based on a standard uncertainty multiplied by a coverage factor of kp = 2, providing a level of confidence of p = 95.45%		

Table 6 Measurement uncertainty based on ETSI TR 100 028