



Prüfbericht-Nr.: <i>Test report no.:</i>	DE2334C9 001	Auftrags-Nr.: <i>Order no.:</i>	1140809_171	Seite 1 von 13 Page 1 of 13
Kunden-Referenz-Nr.: <i>Client reference No.:</i>	-	Auftragsdatum: <i>Order date:</i>	2023-05-23	
Auftraggeber: <i>Client:</i>	FIOR and GENTZ GmbH Dorette von Stern Strasse 5, Lueneburg, 21337, Germany			
Prüfgegenstand: <i>Test item:</i>	Bluetooth Controller			
Bezeichnung / Typ-Nr.: <i>Identification / Type no.:</i>	ET3860			
Auftrags-Inhalt: <i>Order content:</i>	Prüfung der Funkparameter nach FCC & ISSED Test of radio parameters acc. to FCC & ISSED			
Prüfgrundlage: <i>Test specification:</i>	Vollprüfung / Complete test RF exposure evaluation acc. to FCC CFR 47 Part 15 Subpart C §15.247 (i) RF exposure evaluation acc. to RSS-102 issue 5			
Wareneingangsdatum: <i>Date of sample receipt:</i>	2023-07-31	Refer to EUT External Photos_ DE239P74 001		
Prüfmuster-Nr.: <i>Test sample no.:</i>	A003611168-003 to 004			
Prüfzeitraum: <i>Testing period:</i>	2023-12-06 - 2023-12-08			
Ort der Prüfung: <i>Place of testing:</i>	Nürnberg Nuremberg			
Prüflaboratorium: <i>Testing laboratory:</i>	Wireless Labor Wireless Test Lab			
Prüfergebnis*: <i>Test result*:</i>	Pass			
geprüft von: <i>tested by:</i>	genehmigt von: <i>authorized by:</i>			
Datum: <i>Date:</i>	Datum: <i>Issue date:</i>			
Stellung / Position	Stellung / Position			
Sonstiges / Other:	-			
Zustand des Prüfgegenstandes bei Anlieferung: <i>Condition of the test item at delivery:</i>	Prüfmuster vollständig und unbeschädigt Test item complete and undamaged			
* Legende:	1 = sehr gut P(ass) = entspricht o.g. Prüfgrundlage(n)	2 = gut F(ail) = entspricht nicht o.g. Prüfgrundlage(n)	3 = befriedigend F(ail) = entspricht nicht o.g. Prüfgrundlage(n)	4 = ausreichend N/A = nicht anwendbar
* Legende:	1 = very good P(ass) = passed a.m. test specification(s)	2 = good F(ail) = failed a.m. test specification(s)	3 = satisfactory N/A = not applicable	4 = sufficient N/T = nicht getestet 5 = poor N/T = not tested
Dieser Prüfbericht bezieht sich nur auf das o.g. Prüfmuster und darf ohne Genehmigung der Prüfstelle nicht auszugsweise vervielfältigt werden. Dieser Bericht berechtigt nicht zur Verwendung eines Prüfzeichens. <i>This test report only relates to the a. m. test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any test mark.</i>				

Prüfbericht-Nr.: DE2334C9 001
Test report no.:

Seite 2 von 13
Page 2 of 13

Anmerkungen Remarks

1	Alle eingesetzten Prüfmittel waren zum angegebenen Prüfzeitraum gemäß eines festgelegten Kalibrierungsprogramms unseres Prüfhauses kalibriert. Sie entsprechen den in den Prüfprogrammen hinterlegten Anforderungen. Die Rückverfolgbarkeit der eingesetzten Prüfmittel ist durch die Einhaltung der Regelungen unseres Managementsystems gegeben. Detaillierte Informationen bezüglich Prüfkonditionen, Prüfequipment und Messunsicherheiten sind im Prüflabor vorhanden und können auf Wunsch bereitgestellt werden. <i>The equipment used during the specified testing period was calibrated according to our test laboratory calibration program. The equipment fulfils the requirements included in the relevant standards. The traceability of the test equipment used is ensured by compliance with the regulations of our management system.</i> <i>Detailed information regarding test conditions, equipment and measurement uncertainty is available in the test laboratory and could be provided on request.</i>
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3	Prüfklausel mit der Note * wurden an qualifizierte Unterauftragnehmer vergeben und sind unter der jeweiligen Prüfklausel des Berichts beschrieben. Abweichungen von Prüfspezifikation(en) oder Kundenanforderungen sind in der jeweiligen Prüfklausel im Bericht aufgeführt. <i>Test clauses with remark of * are subcontracted to qualified subcontractors and described under the respective test clause in the report.</i> <i>Deviations of testing specification(s) or customer requirements are listed in specific test clause in the report.</i>
4	Die Entscheidungsregel für Konformitätserklärungen in diesem Prüfbericht basiert auf der "Null-Grenzwert-Regel" und der "Einfachen Akzeptanz" gemäß ILAC G8:2019 und IEC Guide 115:2021, es sei denn, in der auf Seite 1 dieses Berichts genannten angewandten Norm ist etwas anderes festgelegt oder vom Kunden gewünscht. Dies bedeutet, dass die Messunsicherheit nicht berücksichtigt wird und daher auch nicht im Prüfbericht angegeben wird. <i>The decision rule for statements of conformity in this test report is based on the "Zero Guard Band Rule" and "Simple Acceptance" in accordance with ILAC G8:2019 and IEC Guide 115:2021, unless otherwise specified in the applied standard mentioned on Page 1 of this report or requested by the customer. This means that measurement uncertainty is not taken in account and hence also not declared in the test report.</i>

Prüfbericht-Nr.: DE2334C9 001
Test report no.:

Seite 3 von 13
Page 3 of 13

Produktbeschreibung
Product description

1	Test item	Bluetooth Controller
2	Typ-No.	ET3860
3	Test sample obtaining	☒ Sending by customer ☐ Sampling by TÜV Rheinland Group ☐ others:
4	Serial-No.	-
5	Supported radio technologies	BLE4.2
6	Description of EUT	Automatic ankle joint system NEURO HiSWING R+ has an automatic adjustment function of inclination angle. When a patient goes up/down the ramp, the joint adjusts its angle to compensate for the change inclination angle of the ramp. Using the App, automatic adjustment can be enabled or disabled. The angle of joint can also be manually unlocked by pressing a mechanical button in the joint, and after selecting proper angle, locked again. Joint angle could be changed by +/- 17°.
7	Max RF output power (measured)	4 dBm
8	Operating Frequency (declared)	2402MHz to 2480Hz
9	Channel Bandwidth (declared)	1 MHz
10	Number of Channels	40
11	Modulation	GFSK
12	Rated Voltage / Frequency	4.2V DC
13	Radio Module / Antenna Type	☒ Radio module with antenna on module PCB ☐ Radio module with dedicated antenna ☐ Radio module with user accessible antenna connector
14	Antenna Name	PCB Antenna
15	Antenna Type	☒ Integral antenna ☐ Dedicated antenna ☐ Permanent antenna connector
16	Antenna amount of chains	1

Prüfbericht-Nr.: DE2334C9 001
Test report no.:

Seite 4 von 13
Page 4 of 13

Produktbeschreibung
Product description

17	Antenna Gain (declared)	0 dBi
18	Software Version	5.1.5
19	Hardware Version	1.4.1
20	Used Samples	A003611168-003 to 004
21	Temperature Range	-10° to 40°
22	Environment	Indoor
23	FCC ID: 2BH6Y-ET3860 & IC:32628-ET3860	

Prüfbericht-Nr.: DE2334C9 001

Seite 5 von 13

Test report no.:

Page 5 of 13

Absatz <i>Clause</i>	Anforderungen – Prüfungen / <i>Requirements - Tests</i>	Bemerkungen / <i>Remarks</i>	Ergebnis <i>Result</i>
FCC 15.247 (i)	RF exposure evaluation	-	P ☒ F ☐ N/A ☐ N/T ☐
RSS-102 Issue 5	RF exposure compliance of radiocommunication apparatus	-	P ☒ F ☐ N/A ☐ N/T ☐

Prüfbericht-Nr.: DE2334C9 001
Test report no.:

Seite 6 von 13
Page 6 of 13

Prüfdokumentation
Test documentation

Contents

1	Registration	7
2	EUT Classification	7
2.1	Wireless technologies and frequencies supported by the EUT	7
2.2	Standard specific classification of the EUT	7
2.2.1	Applied standards	7
2.2.2	Exposure conditions	8
3	Test results in detail.....	9
3.1	FCC SAR test exclusion requirements	9
3.2	ISED SAR evaluation exemption requirements.....	10
4	Application form.....	12
5	Change history	13

Prüfbericht-Nr.: DE2334C9 001
Test report no.:

Seite 7 von 13
Page 7 of 13

Prüfdokumentation
Test documentation

1 Registration

The measurement facilities for conducted and radiated disturbance measurements of the TÜV Rheinland LGA Products have been found to be in compliance with the requirements of Section 2.948 of the FCC Rules. Measurement data will be accepted in conjunction with applications for Certification under Parts 15 and 18 of the Commission's Rules.

FCC Registration Number: 939976

Bundesnetzagentur Registration Number: BNetzA-CAB-17/21-16

The measurement facilities are also recognized by Innovation, Science and Economic Development (ISED) Canada to test to Canadian radio equipment requirements.

Company Number: 11235A

CAB Identifier: DE0018

2 EUT Classification

2.1 Wireless technologies and frequencies supported by the EUT

The named technologies are only those falling in the specification of the applied standard.

Technology	Frequency Range (TX)	TX Function	Test report
BLE4.2	2400 – 2483.5 MHz	SISO	DE239P74 001
802.11b,g,n (20/40 MHz)	2400 – 2483.5 MHz		
802.11a,n,ac (20/40/80 MHz)	5170 –5710 MHz		

2.2 Standard specific classification of the EUT

2.2.1 Applied standards

- FCC CFR 47 Part 15 Subpart C §15.247 (i)
- FCC CFR 47 Part 1 Subpart I §1.1307 (b)
- FCC CFR 47 Part 1 Subpart I §1.1310 (limits)
- FCC CFR 47 Part 2 Subpart J §2.1091 (mobile)
- FCC CFR 47 Part 2 Subpart J §2.1093 (portable)
- FCC KDB 447498 D01 v06 – RF Exposure procedures and equipment authorization policies for mobile and portable devices
- RSS-102 issue 5

Prüfbericht-Nr.: DE2334C9 001
Test report no.:

Seite 8 von 13
Page 8 of 13

Prüfdokumentation
Test documentation

2.2.2 Exposure conditions

	Type of exposure
☒	General public exposure
☐	Occupational exposure

	Separation distance – Intended usage location
☒	≤ 20 cm – portable Declared minimum test separation, ensured by enclosure: 5 mm
☒	Body-worn device
☐	Limb-worn device
☐	Head exposure device
☐	Implanted device
☐	> 20 cm
☐	Fixed device
☐	Mobile device

Prüfbericht-Nr.: DE2334C9 001
Test report no.:

Seite 9 von 13
Page 9 of 13

Prüfdokumentation Test documentation

3 Test results in detail

3.1 FCC SAR test exclusion requirements

Limit:

FCC KDB 447498 D01 v06, chapter 4.3.1:

For 100 MHz to 6 GHz and test separation distances ≤ 50 mm, the 1-g and 10-g SAR test exclusion thresholds are determined by the following:

$[(\text{max. power of channel, including tune-up tolerance, mW}) / (\text{min. test separation distance, mm})] \cdot [\sqrt{f}(\text{GHz})]$
 ≤ 3.0 for 1-g SAR, and ≤ 7.5 for 10-g extremity SAR

Evaluation of Compliance:

As it can be seen in the test report DE239P74 001 measured maximum conducted output power is 4dBm, so the same maximum conducted power is considered for the evaluation.

Considering the separation distance of 5 mm (When the minimum test separation distance is < 5 mm, a distance of 5 mm according to 4.1 f of 447498 D01 V06) is applied to determine SAR test exclusion)

Frequency [MHz]	ERP [dBm]	Antenna Gain [dBi]	EIRP (Including Tune-up tolerance) [dBm]	EIRP (Including Tune-up tolerance) [mW]	SAR test exclusion Thresholds	Limit (1-g SAR) [mW]	Limit (10-g SAR) [mW]	Result
2440	4	0	5	3.16	0.9872	3	7.5	Pass

Note: The distance to the patient is 2-5 millimeters & 1 dB tune-up tolerance is declared by the customer.

Result:

The equipment is compliant according to FCC KDB 447498 D01 v06 because the constraint for the output power level at the test separation distance for standalone SAR test exclusion is met.

Prüfbericht-Nr.: DE2334C9 001
Test report no.:

Seite 10 von 13
Page 10 of 13

Prüfdokumentation Test documentation

3.2 ISED SAR evaluation exemption requirements

Limit:

RSS 102 issue 5, chapter 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 Table 1.

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 routine evaluation in Table 1 are multiplied by a factor of 5.
☐	For limb-worn devices where the 10 gram value applies, the exemption limits for routine evaluation in Table 1 are multiplied by a factor of 2.5.
☒	If the operating frequency of the device is between two frequencies located in Table 1, 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 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
☐	Transmitters operating between 0.003-10 MHz, meeting the exemption from routine SAR evaluation, shall demonstrate compliance to the instantaneous limits in Section 4.

Table 1: SAR evaluation — Exemption limits for routine evaluation based on frequency and separation distance^{4.5}

Frequency (MHz)	Exemption Limits (mW)				
	At separation distance of ≤5 mm	At separation distance of 10 mm	At separation distance of 15 mm	At separation distance of 20 mm	At separation distance of 25 mm
≤300	71 mW	101 mW	132 mW	162 mW	193 mW
450	52 mW	70 mW	88 mW	106 mW	123 mW
835	17 mW	30 mW	42 mW	55 mW	67 mW
1900	7 mW	10 mW	18 mW	34 mW	60 mW
2450	4 mW	7 mW	15 mW	30 mW	52 mW
3500	2 mW	6 mW	16 mW	32 mW	55 mW
5800	1 mW	6 mW	15 mW	27 mW	41 mW

Prüfbericht-Nr.: DE2334C9 001
Test report no.:

Seite 11 von 13
Page 11 of 13

Prüfdokumentation Test documentation

Frequency (MHz)	Exemption Limits (mW)				
	At separation distance of 30 mm	At separation distance of 35 mm	At separation distance of 40 mm	At separation distance of 45 mm	At separation distance of ≥50 mm
≤300	223 mW	254 mW	284 mW	315 mW	345 mW
450	141 mW	159 mW	177 mW	195 mW	213 mW
835	80 mW	92 mW	105 mW	117 mW	130 mW
1900	99 mW	153 mW	225 mW	316 mW	431 mW
2450	83 mW	123 mW	173 mW	235 mW	309 mW
3500	86 mW	124 mW	170 mW	225 mW	290 mW
5800	56 mW	71 mW	85 mW	97 mW	106 mW

Considering the separation distance of 5 mm as declared by the customer and a frequency of 2450 MHz the maximum output power at 5 mm distance is 4 mW= 6.02 dBm.

Over linear interpolation the limit for 2402 MHz is given with 4.26 mW $\triangleq$ 6.294 dBm and for 2480 MHz with 3.94 mW $\triangleq$ 5.954 dBm.

Considering 1dB tune up tolerance as declared by the customer.

Evaluation of Compliance:

As it can be seen in test report DE23X7NU 001 the Declared maximum conducted output power is worst power than the measured power. Therefore, declared maximum conducted power is considered for the evaluation.

Frequency [MHz]	ERP [dBm]	Antenna Gain [dBi]	EIRP (Including Tune-up tolerance) [dBm]	EIRP (Including Tune-up tolerance) [mW]	Limit at 2402 MHz [mW]	Limit at 2480 MHz [mW]	Result
2440	4	0	5	3.16	4.26	3.94	Pass

Result:

The equipment is compliant according to RSS 102 issue 5 because the constraint for the output power level at the separation distance for SAR evaluation exemption is met.

Final test result

Pass

Prüfbericht-Nr.: DE2334C9 001
Test report no.:

Seite 12 von 13
Page 12 of 13

Zusatzdokumentation
Additional documentation

4 Application form

The following information was provided by the customer and form the basis for the execution of the tests and the assessment of conformity. The given information can affect the results of both.

Prüfbericht-Nr.: DE2334C9 001
Test report No.:

Seite 13 von 13
Page 13 of 13

Änderungsverzeichnis
Change history

5 Change history

Revision Number	List of revisions	Date of issue
DE2334C9 001	Initial Release	30.09.2024

Note: Latest revision report will replace all previous reports.

Ende des Prüfberichts
End of Test Report