

Prüfbericht-Nr.: <i>Test report no.:</i>	DE25N8RQ 002	Auftrags-Nr.: <i>Order no.:</i>	1199779 50	Seite 1 von 15 Page 1 of 15
Kunden-Referenz-Nr.: <i>Client reference no.:</i>	4500445712	Auftragsdatum: <i>Order date:</i>	2025-09-04	
Auftraggeber: <i>Client:</i>	Richard Wolf GmbH, Pforzheimer Str. 32, 75438 Knittlingen, Deutschland			
Prüfgegenstand: <i>Test item:</i>	CONTROL DEVICE FOR TISSUE REMOVAL			
Bezeichnung / Typ-Nr.: <i>Identification / Type no.:</i>	2209001			
Auftrags-Inhalt: <i>Order content:</i>	Prüfung der Funkparameter nach FCC & ISED <i>Test of radio parameters acc. to FCC & ISED</i>			
Prüfgrundlage: <i>Test specification:</i>	Vollprüfung / Complete test RF exposure evaluation acc. to FCC CFR 47 Part FCC Part 1.1310 acc. to RSS-102 issue 6 December, 2023			
Wareneingangsdatum: <i>Date of sample receipt:</i>	2025-09-16	For reasons of confidentiality, no photos of the EUT are included in this report. For EUT and test setup photos please see the Photo Documentation to this report Number.		
Prüfmuster-Nr.: <i>Test sample no.:</i>	A004105594-001 to 002			
Prüfzeitraum: <i>Testing period:</i>	2025-05-13 - 2026-02-26			
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>	Signiert von: Matthias Kraeutlein		Ausstellungsdatum: <i>Issue date:</i>	Signiert by: Shrinivas Naikar
Stellung / Position:	Sachverständige(r)/Expert		Stellung / Position:	Sachverständige(r)/Expert
Sonstiges / <i>Other:</i>				
Zustand des Prüfgegenstandes bei Anlieferung: <i>Condition of the test item at delivery:</i>	Prüfmuster vollständig und unbeschädigt <i>Test item complete and undamaged</i>			
* Legende:	P(ass) = entspricht o.g. Prüfgrundlage(n)	F(ail) = entspricht nicht o.g. Prüfgrundlage(n)	N/A = nicht anwendbar	N/T = nicht getestet
* Legend:	P(ass) = passed a.m. test specification(s)	F(ail) = failed a.m. test specification(s)	N/A = not applicable	N/T = not tested
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Prüfbericht-Nr.: DE25N8RQ 002
Test report no.:

Seite 2 von 15
Page 2 of 15

Produktbeschreibung
Product description

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. 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 basierend auf numerischen Messergebnissen 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. Zu weiteren Informationen bezüglich des Risikos durch diese Entscheidungsregel siehe ILAC G8:2019. <i>The decision rule for statements of conformity, based on numerical measurement results, 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. For additional information to the resulting risk based of this decision rule please refer to ILAC G8:2019.</i>
5	Wenn auf dem Bericht kein Akkreditierungshinweis aufgebracht ist, wurde der Bericht nicht im akkreditierten Bereich erstellt und ist folglich auch nicht vom EA MLA abgedeckt. Unabhängig davon wurde der Bericht auf Basis der allgemeinen Regeln der ISO/IEC 17000er Reihe erstellt. Mit "#" gekennzeichnete Prüfungen sind nicht Bestandteil der Akkreditierung D-PL-14169-03-00. <i>If there is no accreditation notice on the report, the report has not been produced in the accredited area and is consequently not covered by the EA MLA. Regardless of this, the report has been prepared based on the general rules of the ISO/IEC 17000 series. Tests marked with "#" are not covered by the accreditation D-PL-14169-03-00.</i>

Prüfbericht-Nr.: DE25N8RQ 002
Test report no.:

Seite 3 von 15
Page 3 of 15

Produktbeschreibung
Product description

1	Test item	CONTROL DEVICE FOR TISSUE REMOVAL	
2	Typ-No.	2209001	
3	Identical Types and Application Part.	Type No	Name
		2209101	CONTROL DEVICE FOR TISSUE REMOVAL
		42209002	TISSUE REMOVAL DEVICE FOR URO
		42209102	TISSUE REMOVAL DEVICE FOR URO
4	Test sample obtaining	☒ Sampling by customer ☐ Sampling by TÜV Rheinland Group ☐ others:	
5	Serial-No.	1101132087	
6	Supported radio technologies evaluated in this report	NFC (ISO/IEC 14443A)	
7	Supported radio technologies not evaluated in this report	-	
8	Description of EUT	Recognition, devaluation and parameter transmission of sterile application parts	
9	Max RF output power (declared)	2W with LSA4-SHD antenna	
10	Operating Frequency (declared)	13,56 MHz	
11	Channel Bandwidth (declared)	Not Provided	
12	Number of Channels	1	
13	Modulation	100% ASK	
14	Rated Voltage / Frequency	100VAC to 240VAC (50Hz to 60Hz)	
15	Radio Module Name	CLRC66301HN	
16	FCC-ID (Radio module)	2BS3I-2209101	
17	IC (Radio module)	35058-2209001	
18	Radio Module / Antenna Type	☐ Radio module with antenna on module PCB ☒ Radio module with dedicated antenna ☐ Radio module with user accessible antenna connector	
19	Antenna Name	RFID PCB 64352620	
20	Antenna Type	☒ Integral antenna (designed as a fixed part of the EUT) ☐ Dedicated antenna (removable, obligation to be used) ☐ Permanent antenna connector	
21	Antenna number of chains	1	
22	Antenna Gain Choose an item	Information not available	
23	Software / Firmware	Not Provided	
24	Hardware	Not Provided	
25	Provided Samples	A004105594-001 to 002	
26	Conducted measurements sample	N/A(cond. sample)	
27	Radiated measurements sample	A004105594-001 (rad. sample)	
28	Companion Device used for radio connection with the EUT	EUT in Test Mode. Therefore, no Companion Device was used.	
29	Auxiliary equipment used to set up the EUT	N/A	
30	Data Cable	N/A	
31	I/O Ports	N/A	
32	Temperature Range	+10°C -+35°C	
33	Environment	Indoor	

Prüfbericht-Nr.: DE25N8RQ 002
Test report no.:

Seite 4 von 15
Page 4 of 15

Prüfdokumentation
Test documentation

Contents

1	Registration	5
2	EUT Classification.....	5
2.1	Wireless technologies and frequencies supported by the EUT.	5
2.2	Standard specific classification of the EUT.....	5
3	Test conditions and configurations	6
3.1	Normal environmental test conditions	6
3.2	Equipment modifications.....	6
3.3	Test Modes	7
3.4	Measurement Uncertainty.....	8
4	Test results in detail FCC RF exposure evaluation	9
4.1	Maximum Permissible Exposure Evaluation (MPE) Mobile device or fixed RF source	9
4.2	ISED Maximum Exposure Requirements	11
5	Test Setup Photo	13
6	Equipment List.....	14
6.1	Hardware	14
7	Change history.....	15

Prüfbericht-Nr.: DE25N8RQ 002
Test report no.:

Seite 5 von 15
Page 5 of 15

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.

Technology	Frequency Range (TX)	Supported by the EUT	Evaluated in this report
RFID	13.11 – 14.01 MHz (fc=13.56 MHz)	☒	☒

2.2 Standard specific classification of the EUT

2.2.1 Applied FCC standards

FCC CFR 47 Part FCC Part 1.1310

FCC CFR 47 Part 1 Subpart I §1.1307 (b)

FCC KDB 447498 D04 v01 – Interim General RF Exposure procedures Guidance (Procedures and Equipment Authorization Policies for Mobile and Portable Devices)

2.2.2 Applied ISED standards

RSS-GEN (General Requirements for Compliance of Radio Apparatus)

RSS-102 issue 6 (Radio Frequency (RF) Exposure Compliance of Radiocommunication Apparatus)

Health Canada's Safety Code 6 (2015)

Prüfbericht-Nr.: DE25N8RQ 002
Test report no.:

Seite 6 von 15
Page 6 of 15

Prüfdokumentation
Test documentation

2.2.3 Exposure conditions

	Type of exposure
☒	General public exposure
☐	Occupational exposure

	Separation distance – Intended usage location
☐	< 20 cm – portable
☐	Body-worn device -
☐	Limb-worn device -
☐	Head exposure device -
☐	Implanted device
☒	≥ 20 cm
☒	Fixed device (physically secured at one location, even temporarily) specific mitigation actions are required
☐	Mobile device

3 Test conditions and configurations

3.1 Normal environmental test conditions

Environmental condition	Parameter	Range during test
Temperature	°C	24
Relative humidity	%	35
Supply voltage	100V-240V 50/60Hz	120V / 60 Hz

3.2 Equipment modifications

No modifications were found to be necessary to perform the tests or to achieve compliance.

Prüfbericht-Nr.: DE25N8RQ 002
Test report no.:

Seite 7 von 15
Page 7 of 15

Prüfdokumentation
Test documentation

3.3 Test Modes

Following configurations were used for the test cases:

Test case	Worst case Configuration
Maximum Output Power	200m W

Mode description	Mode configuration
All Modes	No auxiliary equipment was connected to the EUT.
Mode 1: TX-Mode	The RFID function starts immediately after the EUT is turned on
Mode 2: N/A	-
Mode 3: N/A	-
Mode 4: N/A	-

Prüfbericht-Nr.: DE25N8RQ 002
Test report no.:

Seite 8 von 15
Page 8 of 15

Prüfdokumentation
Test documentation

3.4 Measurement Uncertainty

The data and results referenced in this document are true and accurate. The reader is cautioned that there may be errors within the calibration limits of the equipment and facilities. The measurement uncertainty was calculated for all measurements listed in this test report acc. to ETSI TR 100 028-1/-2 and ETSI TS 103 051 (radiated measurements) and is documented in the quality system acc. to ISO/IEC 17025:2017.

Furthermore, component and process variability of devices similar to that tested may result in additional deviation.

The stated values are the expanded uncertainty values, the measured value lies within the assigned range of values with a probability of 95% ($k = 1.96$).

The manufacturer has the sole responsibility of continued compliance of the device.

Test	Value	Unit	Range
Frequency Error	$2.7 \cdot 10^{-8}$	Hz	-
Frequency Stability under low voltage conditions			
Time	$1.1 \cdot 10^{-9}$	s	-
Conducted Carrier Power	1.0	dB	9k-1GHz
Conducted Spurious Emissions (RX/TX)	1.7	dB	1GHz-6GHz
	2.8	dB	6GHz-40GHz
Occupied Bandwidth (OBW)	0.1	%	-
TX Power Spectral Density	4.2	mW	9kHz - 6GHz
	1.6	dB	9kHz - 6GHz
Dwell Time	$4.6 \cdot 10^{-7}$	Hz	-
Frequency Separation			-
Measurement of conducted emissions at the power supply connection to LISN	2.3	dB	9kHz – 150kHz
	2.2	dB	150kHz – 30MHz
Measurement of the field strength at distance 3m	1.6	dB	9k-150kHz
	4.5	dB	30-1000MHz
	5	dB	1-6GHz
	5.3	dB	6-40GHz
Temperature	0.8	K	-
Humidity	4	%	-
Voltage (AC/DC)	1.0	%	-

Measured value	Limit	Extended measurement uncertainty ($k=1.96$)	Confidence interval (95%)
19 dBm @ 2.48GHz	20 dBm	1.7 dB	17.3 dBm – 20.7 dBm

Prüfdokumentation
Test documentation

4 Test results in detail FCC RF exposure evaluation

Radio frequency devices operating under the provisions of FCC CFR 47 Part 15 are subject to the radio frequency radiation exposure requirements specified in §§ 1.1307(b), 1.1310, 2.1091, and 2.1093, as appropriate.

4.1 Maximum Permissible Exposure Evaluation (MPE) Mobile device or fixed RF source

4.1.1 Description

For operations within the frequency range of 300 kHz and 6 GHz (inclusive), the limits for maximum permissible exposure (MPE), derived from whole-body SAR limits and listed in Table 1 to § 1.1310(e)(1), may be used instead of whole-body SAR limits to evaluate the environmental impact of human exposure to RF radiation as specified in § 1.1307(b) of this part, except for portable devices as defined in § 2.1093 of this chapter as these evaluations shall be performed according to the SAR provisions in § 2.1093.

4.1.2 Limits

Limits for Maximum Permissible Exposure (MPE) to radiofrequency electromagnetic fields from §1.1310(e)(1) are shown in the table below.

Table 1 to § 1.1310(e)(1) - Limits for Maximum Permissible Exposure (MPE)				
Frequency range (MHz)	Electric field strength (V/m)	Magnetic field strength (A/m)	Power density (mW/cm ²)	Averaging time (minutes)
(i) Limits for Occupational/Controlled Exposure				
0.3-3.0	614	1.63	*(100)	≤6
3.0-30	1842/f	4.89/f	*(900/f ²)	<6
30-300	61.4	0.163	1.0	<6
300-1,500			f/300	<6
1,500-100,000			5	<6
(ii) Limits for General Population/Uncontrolled Exposure				
0.3-1.34	614	1.63	*(100)	<30
1.34-30	824/f	2.19/f	*(180/f ²)	<30
30-300	27.5	0.073	0.2	<30
300-1,500			f/1500	<30
1,500-100,000			1.0	<30

f = frequency in MHz. * = Plane-wave equivalent power density.

Prüfbericht-Nr.: DE25N8RQ 002
Test report no.:

Seite 10 von 15
Page 10 of 15

Prüfdokumentation
Test documentation

4.1.3 Evaluation for Technologies assumed to be not in far field at the distance d

In the near-field zone, both the unperturbed electric- and magnetic-field strengths shall be measured, since there is no simple relationship between these two quantities.

At 50 MHz, the near field extends out to about 1 m. For frequencies below 50 MHz and within this distance, the magnetic field is the predominant field component of loop antennas. Therefore, only the H-field was measured.

As some limits are frequency dependent, for each Band the limit is calculated based on the lowest band edge frequency f_{Lowest} .

4.1.3.1 Test setup

Test method	Radiated		
EUT	A004105594-001 (rad. sample)		
Environmental Cond.	Normal		
Chamber details	☐ Shielded room ☒ 3m Fully Anechoic Chamber (FAC) ☐ 10m Semi Anechoic Chamber (SAC)		
Measurement positioning	Distance: ☒ 20cm ☐ 3m ☐ 10m	EUT height: ☒ 0.4m ☐ 0.8m ☐ floor standing	Antenna height: ☐ 1.5m ☐ 1m to 4m – height scan ☒ around the EUT
Companion device	EUT in Test Mode. Therefore, no Companion Device was used.		
Operation mode	☒ 1: TX-Mode ☐ 3: N/A ☐ 2: N/A ☐ 4: N/A		
Further parameters	-		
Test engineer	Matthias Kräutlein		

4.1.3.2 Test results

f [MHz]	RBW [kHz]	Integration [MHz]	Sweep Time [ms]	AVG [ms]	H [A/m]	f_{Lowest} [MHz]	H_L [A/m]	H / H_L
13.56	9	12 – 16	34	992	0.002024	13.120	0.373	0.054

4.1.4 Final test result

Final test result	Pass
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Prüfbericht-Nr.: DE25N8RQ 002
Test report no.:

Seite 11 von 15
Page 11 of 15

Prüfdokumentation
Test documentation

4.2 ISED Maximum Exposure Requirements

According to RSS-102 issue 6, Industry Canada has adopted the SAR and RF field strength limits established in Health Canada's RF exposure guideline, Safety Code 6 (2015) and its Notice. Any updates to Safety Code 6 and/or its Notice will supersede the values outlined in RSS-102 issue 6

4.2.1 Electric Field Strength, Magnetic Field Strength and Power Density (10 MHz - 300 GHz)

According to the limits of human exposure in Safety Code 6 clause 2.2.2:

To ensure compliance with the basic restrictions at frequencies between 10 MHz and 300 GHz, the reference levels for electric- and magnetic-field strength and power density must be complied with.

Table 7: RF field strength and power density limits for devices used by the general public (uncontrolled environment)

Frequency range (MHz)	Electric field (V _{RMS} /m)	Magnetic field (A _{RMS} /m)	Power density (W/m ²)	Reference period (minutes)
10-20	27.46	0.0728	2	6
20-48	$58.07 / f^{0.25}$	$0.1540 / f^{0.25}$	$8.944 / f^{0.5}$	6
48-300	22.06	0.05852	1.291	6
300-6000	$3.142 f^{0.3417}$	$0.008335 f^{0.3417}$	$0.02619 f^{0.6834}$	6
6000-15000	61.4	0.163	10	6
15000-150000	61.4	0.163	10	$616000 / f^{1.2}$
150000-300000	$0.158 f^{0.5}$	$4.21 \times 10^{-4} f^{0.5}$	$6.67 \times 10^{-5} f$	$616000 / f^{1.2}$

Note: f is frequency in MHz.

Table 8: RF field strength and power density limits for controlled-use devices (controlled environment)

Frequency range (MHz)	Electric field (V _{RMS} /m)	Magnetic field (A _{RMS} /m)	Power density (W/m ²)	Reference period (minutes)
10-20	61.4	0.163	10	6
20-48	$129.8 / f^{0.25}$	$0.3444 / f^{0.25}$	$44.72 / f^{0.5}$	6
48-100	49.33	0.1309	6.455	6
100-6000	$15.60 f^{0.25}$	$0.04138 f^{0.25}$	$0.6455 f^{0.5}$	6
6000-15000	137	0.364	50	6
15000-150000	137	0.364	50	$616000 / f^{1.2}$
150000-300000	$0.354 f^{0.5}$	$9.40 \times 10^{-4} f^{0.5}$	$3.33 \times 10^{-4} f$	$616000 / f^{1.2}$

Prüfbericht-Nr.: DE25N8RQ 002
Test report no.:

Seite 12 von 15
Page 12 of 15

Prüfdokumentation Test documentation

4.2.2 Evaluation for Technologies assumed to be not in far field at the distance d

In the near-field zone, both the unperturbed electric- and magnetic-field strengths shall be measured, since there is no simple relationship between these two quantities.

At 50 MHz, the near field extends out to about 1 m. For frequencies below 50 MHz and within this distance, the magnetic field is the predominant field component of loop antennas. Therefore, only the H-field was measured.

As some limits are frequency dependent, for each Band the limit is calculated based on the lowest band edge frequency f_{Lowest} .

4.2.2.1 Test setup

Test method	Radiated		
EUT	A004105594-001 (rad. sample)		
Environmental Cond.	Normal		
Chamber details	☐ Shielded room ☒ 3m Fully Anechoic Chamber (FAC) ☐ 10m Semi Anechoic Chamber (SAC)		
Measurement positioning	Distance: ☒ 20cm ☐ 3m ☐ 10m	EUT height: ☒ 0.4m ☐ 0.8m ☐ floor standing	Antenna height: ☐ 1.5m ☐ 1m to 4m – height scan ☒ around the EUT
Companion device	EUT in Test Mode. Therefore, no Companion Device was used.		
Operation mode	☒ 1: TX-Mode ☐ 3: N/A ☐ 2: N/A ☐ 4: N/A		
Further parameters	-		
Test engineer	Matthias Kräutlein		

4.2.2.2 Test results

f [MHz]	RBW [kHz]	Integration [MHz]	Sweep Time [ms]	AVG [min]	H [A/m]	f_{Lowest} [MHz]	H_L [A/m]	H / H_L
13.56	10	13 – 14	46	6	0.003952	13.2	0.0728	0.054

4.2.2.3 Single RF source

The equipment meets the requirements according to Safety Code 6 clause 2.2.2 since the magnetic field strength is below the applicable limit.

4.2.3 Final test result

Final test result	Pass
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Prüfbericht-Nr.: DE25N8RQ 002
Test report no.:

Seite 13 von 15
Page 13 of 15

Fotodokumentation
Photo documentation

5 Test Setup Photo

For reasons of confidentiality, no photos of the EUT are included in this report.
For EUT and test setup photos please see the Photo Documentation to this report Number.

Prüfbericht-Nr.: DE25N8RQ 002
Test report no.:

Seite 14 von 15
Page 14 of 15

Liste der verwendeten Prüfmittel
List of used test equipment

6 Equipment List

6.1 Hardware

Prüfmittel Test equipment		Prüfmittel-Nr. / ID- Nr. Equipment-No. / ID- No.	Letzte Kalibrierung Last calibration		Nächste Kalibrierung Next calibration
Fully Anechoic Room	Albatross Projects GmbH	2959749	19.02.2026	*	19.04.2026
Selective Radiation Meter SRM-3006	Narda Safety Test Solutions	2729050	03.07.2023		03.07.2026

*Equipment only verified and not calibrated

Prüfbericht-Nr.: DE25N8RQ 002
Test report no.:

Seite 15 von 15
Page 15 of 15

Änderungsverzeichnis
Change history

7 Change history

Revision Number	List of revisions
002	Type numbers & antenna name corrected
001	Initial Release
Note: Latest revision report will replace all previous reports.	

Ende des Prüfberichts
End of Test Report