



RF - TEST REPORT

- Human Exposure -

Type / Model Name : Microjet (debritom+)

Product Description : Part of Microjet Wound Therapy System

Applicant : Medaxis AG

Address : Bahnhofstrasse 9
Baar, Zug 6340 Switzerland

Manufacturer : Medaxis AG

Address : Bahnhofstrasse 9
Baar, Zug 6340 Switzerland

Test Result according to the standards
listed in clause 1 test standards:

POSITIVE

Test Report No. : **80273657-01 Rev_1**

29. June 2026

Date of issue



Deutsche
Akkreditierungsstelle
D-PL-12030-01-00

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1 TEST STANDARDS

The tests were performed according to following standards:

FCC Rules and Regulations Part 1, Subpart I - Procedures Implementing the National Environmental Policy Act of 1969

KDB 447498 D04 v01

RF Exposure procedures and equipment authorisation policies for mobile and portable devices, November 29, 2021.

ANSI C95.1: 2005

IEEE Standard for Safety Levels with respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz

ETSI TR 100 028 V1.3.1: 2001-03,

Electromagnetic Compatibility and Radio Spectrum Matters (ERM);
Uncertainties in the Measurement of Mobile Radio Equipment
Characteristics—Part 1 and Part 2

2 EQUIPMENT UNDER TEST

2.1 Information provided by the Client

Please note, we do not take any responsibility for information provided by the client or his representative which may have an influence on the validity of the test results.

2.2 Sampling

The customer is responsible for the choice of sample. Sample configuration, start-up and operation is carried out by the customer or according to his/her instructions.

2.3 Photo documentation of the EUT

Detailed photos see ATTACHMENT A and ATTACHMENT B

ATTACHMENT A: External views

ATTACHMENT B: Internal views

2.4 Equipment type

RFID / BLE device, fixed equipment

2.5 Short description of the equipment under test (EUT)

Microjet Wound Therapy System is a medical device with high precision micro water jet technology. The compact system produces a fine waterjet to clean acute and chronic wounds in a precise and tissue-preserving manner. The Microjet Wound Therapy System is intended for use on patients in professional care settings by a medical professional.

RFID technology 13.56 MHz
BLE technology

Number of tested samples: 1
Serial number: 00122

2.6 Operation frequency and channel plan

The operating frequency of the RFID is 13.553 MHz to 13.567 MHz on 1 channel.

The operating frequency of the BLE is 2402 MHz to 2480 MHz.

Channel plan:

Channel	Frequency	Channel	Frequency
37	2402	18	2442
0	2404	19	2444
1	2406	20	2446
2	2408	21	2448
3	2410	22	2450
4	2412	23	2452
5	2414	24	2454
6	2416	25	2456
7	2418	26	2458
8	2420	27	2460
9	2422	28	2462
10	2424	29	2464
38	2426	30	2466
11	2428	31	2468
12	2430	32	2470
13	2432	33	2472
14	2434	34	2474
15	2436	35	2476
16	2438	36	2478
17	2440	39	2480

Note: the marked frequencies are determined for final testing.

2.7 Transmit operating modes

RFID:

RFID active (13.56 MHz)

BLE

The EUT uses GFSK modulation and may provide following data rates:

- 1 Mbps

(Mbps = Megabits per second)

2.8 EUT configuration

The following peripheral devices and interface cables were connected during the measurements:

- Debitrom+ pump Model: REF 2000.020x
- Debitrom+ handpiece Model: REF 2000.000x

2.9 Power supply system utilised

Power supply voltage : 100 – 240 V, 50 Hz / 60 Hz

All tests were carried out with a supply voltage of 120 V, 60 Hz unless otherwise stated. Exceptions are described in the detailed test conditions.

The test report merely corresponds to the test sample. It is not permitted to copy extracts of these test results without the written permission of the test laboratory.

3 TEST RESULT SUMMARY

FCC Rule Part	Description	Result
KDB 447498, 2.1.2	1-mW Test Exemption	passed
KDB 447498, 2.2.1	1-mW Test Exemption for Multiple Sources	passed

3.1 Revision history of test report

Test report No	Rev.	Issue Date	Changes
80273657-01	0	18 February 2026	Initial test report
80273657-01	1	29 June 2026	Change MPE contemplation to 1-mW Test Exemption

The test report with the highest revision number replaces the previous test reports.

3.2 Final assessment

The equipment under test fulfills the requirements cited in clause 1 test standards.

Date of receipt of test sample : acc. to storage records

Testing commenced on : 26 January 2026

Testing concluded on : 26 January 2026

Checked by:


Jürgen
Pessinger
2026.06.30
07:27:18 +02'00'

Jürgen Pessinger
Team Lead Radio

Tested by:


Digital signiert von
Markus Friedl
DN: cn=Markus Friedl
Grund: I am the author of
this document
Datum: 2026.06.29
17:26:43 +02'00'

Markus Friedl
Radio Team

4 TEST ENVIRONMENT

4.1 Address of the test laboratory

CSA Group Bayern GmbH
Straubinger Straße 100
94447 Plattling
GERMANY

4.2 Environmental conditions

During the measurement the environmental conditions were within the listed ranges:

Temperature: 15 - 35 °C

Humidity: 30 - 60 %

Atmospheric pressure: 86 - 106 kPa

4.3 Statement of the measurement uncertainty

The data and results referenced in this document are true and accurate. It is noted that the expanded measurement uncertainty corresponds to the measurement results from the standard measurement uncertainty multiplied by the coverage factor $k = 2$. The true value is located in the corresponding interval with a probability of 95 %. The measurement uncertainty was calculated for all measurements listed in this test report on basis of the ETSI Technical Report TR 100 028 Electromagnetic compatibility and Radio spectrum Matters (ERM); Uncertainties in the measurement of mobile radio equipment characteristics; Part 1 and Part 2. The results are documented in the quality system acc. to DIN EN ISO/IEC 17025. Furthermore, component and process variability of devices similar to that tested may result in additional deviation. The manufacturer has the sole responsibility of continued compliance of the device.

4.4 Conformity Decision Rule

The applied conformity decision rule is based on ILAC G8:09/2019 clause 4.2.1 Binary Statement for Simple Acceptance Rule ($w = 0$).

Details can be found in the procedure CSA_B_V50_29.

5 HUMAN EXPOSURE

5.1 RF Exposure Test Exemptions for Single Source

5.1.1 Applicable standard

RF Exposure Procedures and Equipment Authorization Policies for Mobile and Portable Devices

5.1.2 1-mW Test Exemption

Per § 1.1307(b)(3)(i)(A), a single RF source is exempt RF device (from the requirement to show data demonstrating compliance to RF exposure limits, as previously mentioned) if the available maximum time-averaged power is no more than 1 mW, regardless of separation distance.

This exemption applies to all operating configurations and exposure conditions, for the frequency range 100 kHz to 100 GHz, regardless of fixed, mobile, or portable device exposure conditions. This is a standalone exemption, and it cannot be applied in conjunction with any other test exemption.

RFID:

The result is taken from the test report "80273657-00 Rev_1" issued by CSA Group Bayern GmbH (Address: Straubinger Straße 100, 94447 Plattling, Germany). CSA Group Bayern is an accredited testing laboratory.

$$\text{EIRP[dBm]} = \text{E[dB}\mu\text{V/m]} + 20 \log(d[\text{m}]) - 104.77$$

where:

- E is the field strength in dB μ V/m;
- d is the measurement distance in m;
- EIRP is the equivalent isotropically radiated power in dBm.

Frequency [MHz]	Measured Field Strength [dB μ V/m @ 3m]	Calculated EIRP [dBm]	Calculated EIRP [mw]	RF Exposure Limit [mW]	Result
13.56	66.5	-28.7	0.00135	1	passed

BLE:

The RF output power is taken from the test report 80259863-00 Rev_0 issued by CSA Group Bayern GmbH (Address: Straubinger Straße 100, 94447 Plattling, Germany). CSA Group Bayern is an accredited testing laboratory.

Radiated Measurement – EIRP:

-7 dBm (2402 MHz), -5.3 dBm (2480 MHz)

Maximum EIRP:	-5.30 dBm	0.3 mW
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max. EIRP (dBm)	EIRP (mW)	RF Exposure Limit [mW]	Result
-5.30	0.30	1.0	passed

The requirements are **FULFILLED**.

Remarks: Conclusion: SAR evaluation is not needed.

5.2 RF Exposure Test Exemptions for Simultaneous Transmission Sources

5.2.1 1-mW Test Exemption for Multiple Sources

As discussed in § 1.1307(b)(3)(ii)(A), the 1-mW exemption intended for single transmitters may be also applied to simultaneous transmission conditions, within the same host device, according one of the following criteria:

- a) When maximum available power each individual transmitting antenna within the same time averaging period is ≤ 1 mW, and the nearest parts of the antenna structures of the simultaneously operating transmitters are separated by at least 2 cm
- b) When the aggregate maximum available power of all transmitting antennas is ≤ 1 mW in the same time-averaging period. This exemption may not be combined with any other exemption

Simultaneous transmission:

RFID

Maximum at 13.56 MHz; 0.00135 mW

BLE

Maximum output power at 2480 MHz; 0.30 mW

$$0.00135 \text{ mW} + 0.30 \text{ mW} = 0.30135 \leq 1 \text{ mW}$$

The requirements are **FULFILLED**.

Remarks: None
